UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

In re Mylan N.V. Securities Litigation

16-CV-7926 (JPO)

OPINION AND ORDER

J. PAUL OETKEN, District Judge:

This case is a securities fraud class action against Mylan N.V. ("Mylan" or "Defendant") and several of its current and former officers (the "Individual Defendants"). Mylan is a publicly traded firm which operates as a large pharmaceutical manufacturer and distributor. Plaintiffs are purchasers of Mylan securities who challenge various statements by Mylan and its agents as omitting allegedly illegal conduct on the part of Mylan, diminishing the value of their shares. The liability theory advanced by Plaintiffs reflects "claims within claims" — that Plaintiffs misled investors by obscuring underlying violations of antitrust law and regulatory law. Plaintiffs offer three such claims: one alleging that Mylan's statements to investors became misleading due to its antitrust violations in marketing the EpiPen; the second based on the theory that Mylan misled investors about its statutory rebating practices; and the third alleging that Mylan's statements to investors about the generic drug market were misleading due to its participation in an antitrust conspiracy in the generics market.

Before the Court are Defendant's motion for summary judgment as to all claims and Plaintiffs' motion for partial summary judgment on certain elements of the second claim. For the reasons that follow, Defendants' motion for summary judgment is granted and Plaintiffs' motion for partial summary judgment is denied.

I. Background

Plaintiffs in this matter are a certified class under Federal Rule 23(b)(3) defined as:

> All persons or entities that purchased Mylan N.V. and/or Mylan's N.V.'s predecessor, Mylan, Inc., common stock between February 21, 2012 and May 23, 2019, both dates inclusive, excluding Defendants, current and former officers and directors of Mylan, members of their immediate families and their legal representatives, heirs, successors or assigns, and any entity in which Defendants have or had a controlling interest.

(ECF No. 140 ("MTD Op. III") at 14.) Plaintiffs challenge statements made by Mylan as materially misleading to investors under Section 10(b) of the Securities Exchange Act of 1934, 15 U.S.C. § 78j(b), and Rule 10b-5, 17 C.F.R. § 240.10b-5, for three reasons.[1]

First, Plaintiffs claim that certain of Mylan's statements to investors were materially misleading because they either implicitly denied, or failed to disclose the existence of, various anti-competitive agreements between Mylan and various third-party payors and health plans relating to EpiPen, which were allegedly illegal under either Section 1 or Section 2 of the Sherman Act. These claims are referred to as the "EpiPen Antitrust Claims."

Second, Plaintiffs argue that statements by Mylan were materially misleading because they failed to disclose that Mylan, in fact, had to rebate the EpiPen at a lower rate than it suggested. This allegedly resulted in injury to shareholders as evidenced by the fact that Mylan eventually entered a settlement with the Department of Justice as part of a separate litigation. This part the argument is mechanically and procedurally like the first, but it alleges an underlying violation of the Medicare Drug Rebate Program (MDRP), a subsidiary component of the federal Medicaid scheme. These are the "MDRP Claims."

[1] Plaintiffs assert liability claims against various officers and former officers employed by Mylan during the relevant period under Section 20(a) of the Exchange Act, 15 U.S.C. § 78t(a) based on substantially the same allegations and course of conduct.

Third, Plaintiffs claim that certain statements by Mylan were misleading because they failed to disclose alleged market allocation or price-fixing conspiracies involving numerous generic drugs. These claims are the "Generic Drug Antitrust Claims."

This Court has issued three opinions partially denying Defendants' motions to dismiss for failure to state a claim. First, the Court for the most part permitted Plaintiffs' claims regarding EpiPen competition, EpiPen's MDRP classification for rebate rates, and antitrust claims to proceed, while dismissing certain claims under Israeli law and claims based on statements about a firm's general reputation that qualify as nonactionable puffery. (*See* ECF No. 69 ("MTD Op. I") at 20 – 21 (quoting *City of Pontiac Policemen's & Firemen's Ret. Sys. v UBS AG*, 752 F.3d 173, 183 (2d Cir. 2014) (internal citation omitted)); 36 – 40.) The Court also dismissed Plaintiffs' claims that certain intellectual property litigation settlements involving the EpiPen amounted to antitrust violations. *See id.* at 27 (citing *F.T.C. v. Activis, Inc.*, 570 U.S. 136, 139 (2013)). In reaching these conclusions, the Court recognized the somewhat unusual posture in this case — which features three distinct iterations of a "claim within a claim" — stating:

> The Complaint alleges that Mylan's statements were misleading because they failed to disclose that *illegal means* had inflated Mylan's margins and altered the market. Nothing in the Complaint explains why Mylan's statements would be materially misleading if the [challenged] agreements [or rebating conduct] were, as a legal matter, not unlawfully anticompetitive [or violative of the MDRP statute].

MTD Op. I at 30 (emphasis in original).

In its second pass at this litigation, the Court again permitted the lion's share of Plaintiffs' allegations to proceed past another motion to dismiss and revived, based on amended pleading, a claim about the generic drug Doxy DR. But it also clarified an important requirement for Plaintiffs, especially with regard to their generic drug antitrust claims. The Court dismissed certain parts of the generic drug allegations as insufficiently supported by any plausible scienter

inference with respect to a number of generic drugs.[2] The Court permitted many of Plaintiffs' allegations about generic drugs to survive the motion to dismiss on the basis of Plaintiffs' representations that they would rely on direct evidence of an agreement to fix the generics market in the form of testimony by a whistle-blowing former Mylan employee. The Court observed, however, that without this and as the litigation developed, Plaintiffs would have to prove their generics case "on a drug-by-drug basis." (*See* ECF No. 102 ("MTD Op. II") at 14 – 15.)

The Court's third foray into this case continued to permit many of Plaintiffs' claims to survive, but the Court dismissed claims related to 20 different generic drugs based on the above principle. As the Court explained:

> This Court has previously dismissed Plaintiffs' generic drug allegations for failing to meet the evidentiary standards required by . . . the Sherman Act. Even considering Plaintiffs' position that the generic drug allegations should be assessed as a whole to support the broader allegation that "virtually all" of Mylan's generic drugs were affected by anticompetitive activity, that evidentiary standard *must still be met*.

See MTD Op. III at 8 (emphasis added). Thus, the Court held that Plaintiffs were responsible for pleading and, later proving, their case on a drug-by-drug basis. The Court again explained that "[a]llegations about individual generic drugs that fall short of the evidentiary minimum required by the Sherman Act cannot support the notion that 'virtually all' of Mylan's generic drugs were

[2] *See, e.g.* MTD Op. II at 20–22 (dismissing generic drug allegations related to the Doxy Mono, glipizide-metformin, and verapamil). The Court held that, in order to (a) show predicate unlawful conduct such that any statement challenged could be material and (b) show a plausible inference of scienter, Plaintiffs needed to challenge particular agreements that they could establish both existed and influenced the prices for the at-issue generic drugs. The Court did so because Plaintiffs sought to rely on what would be an impermissible inference: that because Defendants had engaged in some antitrust conspiracies, a larger antitrust conspiracy could be inferred and held to apply to all drugs in the generic category.

affected by unlawful anticompetitive conduct." *Id.* at 9. This was so because, first, it would be impermissible to draw any inference of market-wide liability based on examples of specific liability, and, second, Plaintiffs bore not only the burdens associated with the Sherman Act but also the additional burden of showing scienter as to this wrongdoing under the securities laws. *See id.* at 8 – 10, 12.

Following discovery and class certification, the parties now cross-move for summary judgment and, in connection with those motions, also ask the court to resolve various motions *in limine*. Defendant Mylan and the Personal Defendants move for summary judgment as to each of Plaintiffs' bases for liability. Defendants first challenge the existence of a predicate statutory violation of either the Sherman Act or the MDRP statute. Second, the argue that even if such a violation did exist, summary judgment would still be appropriate for want of scienter, a showing of materiality, or loss causation. Plaintiffs move for partial summary judgment as to their MDRP-related claims, seeking a judgment that (1) Mylan did misclassify the EpiPen for drug rebate purposes; (2) this was omitted in Mylan's disclosures and was material; and (3) Mylan acted with the requisite scienter that it was violating the MDRP in so doing.

I. Legal Standards

A. Summary Judgment Standard

To survive summary judgment, nonmovants must raise a genuine issue of material fact. Fed. R. Civ. P. 56(c). To raise such an issue requires "more than simply show[ing] that there is some metaphysical doubt as to the material facts." *Caldarola v. Calabrese*, 298 F.3d 156, 160 (2d Cir. 2002) (quoting *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986). Further, in so doing, nonmovants "may not rely on conclusory allegations or unsubstantiated speculation." *Fujitsu Ltd. v. Fed. Express Corp.*, 247 F.3d 423, 428 (2d. Cir. 2001) (internal citations omitted). Rather, they "must offer some hard evidence showing that

[their] version of events is not wholly fanciful." *D'Amico v. City of New York*, 132 F.3d 145, 149 (2d Cir. 1998). The movant can prevail if, after discovery, "there is no genuine issue as to any material fact" such that a reasonable juror could find for the nonmovant. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). If the movant does produce evidence tending to exclude the possibility of a genuine dispute of material fact, "the nonmoving party must come forward with 'specific facts showing that there is a *genuine issue for trial.*'" *Matsushita*, 475 U.S. at 586 (quoting Fed. R. Civ. P. 56(e)) (emphasis in original). If "the record taken as a whole could not lead a rational trier of fact to find for the non-moving party," then there is no genuine issue of fact for trial, and the court should grant summary judgment in favor of the movant. *Id.* (citing *First Nat. Bank of Ariz. v. Cities Service Co*., 391 U.S. 253, 288 (1968)).

B. Securities Fraud Standard

Plaintiffs bear the burden of establishing a genuine issue of fact with respect to each of the six elements of their claims, all ultimately arising under Section 10(b) of the Exchange Act: (1) a material misrepresentation or an omission; (2) scienter or knowledge; (3) a connection with the purchase or sale of a security; (4) reliance; (5) economic loss; and (6) loss causation. *See Dura Pharms., Inc. v. Broudo*, 544 U.S. 336, 341 – 42 (2005).

As a threshold matter, establishing the first element of material misstatement or omission requires evidence that a reasonable juror could conclude "prove[d] [defendants] made a false statement or omission of material fact." *In re IBM Sec. Litig.*, 163 F.3d 102, 106 – 07 (2d Cir. 1998). Not all omissions or misrepresentations count; the challenged statement must also be material. A statement is material if there is "a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available." *Basic v. Levinson*, 485 U.S. 224, 231–32 (1988).

To survive summary judgment on the element of scienter, a plaintiff must adduce evidence tending to show that the challenged statement or omission was made either with knowledge or with "willful, deliberate, or reckless disregard for the truth that is the equivalent of knowledge." *Lanza v. Drexel & Co.*, 479 F.2d 1277, 1305 (2d Cir. 1973). At minimum, a plaintiff must illustrate "facts supporting a strong inference of conscious recklessness i.e., a state of mind approximating actual intent," but evidence tending to show only "a heightened form of negligence" fails to establish scienter in a manner sufficient to survive a Rule 56 motion. *Setzer v. Omega Healthcare Invs., Inc.*, 968 F.3d 204, 213 (2d Cir. 2020)). Recklessness or reckless conduct is conduct that, beyond just unreasonable, is "highly unreasonable, and amounts to 'an extreme departure from the standards of ordinary care.'" *City of N. Miami Beach Police Officers' & Firefighters' Ret. Plan v. Nat'l Gen. Hldngs. Corp.*, 2021 WL 212337, at *8 (Jan. 21, 2021) (quoting *Kalnit v. Eichler*, 264 F.3d 131, 142 (2d Cir. 2001) (internal citations omitted)).

The element of loss causation requires plaintiffs to produce evidence supporting either a "corrective disclosure" or "materialization of the risk" theory of injury. *See In re Omnicom Grp., Inc. Sec. Litig.*, 597 F.3d 501, 511, 513 (2d Cir. 2010) ("*Omnicom II*"). A "corrective disclosure" is one that reveals "the falsity" of a challenged misstatement by revealing new information to the market. *See In re Omnicom Grp., Inc. Sec. Litig.*, 541 F. Supp. 2d 546, 551 – 52 (S.D.N.Y. 2008) ("*Omnicom I*"). Under the "materialization of the concealed risk" theory, the concealed risk must (1) have actually materialized, (2) have been known to the defendant, and (3) not have been known to the public. *See In re Moody's Corp. Sec. Litig.*, 2013 WL 4516788, at *10 (S.D.N.Y. Aug. 23, 2013). For either theory, plaintiffs must provide a sufficient quantum of evidence to permit the court to "disaggregate" the effects of the challenged statements or omissions from the background noise of market information. *See id.*

II. EpiPen Antitrust Claims

A. Background

1. Challenged Statements

The first set of Plaintiffs' claims concern statements that were allegedly rendered misleading due to Mylan's being part of a variety of antitrust conspiracies related to the marketing of the EpiPen. (*See* ECF No. 334 ("P. Memo.") at 15 – 16.) It is undisputed that, during the relevant period, Mylan made a variety of statements to shareholders. Of these, Plaintiffs have narrowed their challenge to "Statements Explaining the Market" and "Statements Explaining Income." In its three opinions partially denying Defendants' 12(b)(6) motions to dismiss for failure to state a claim, the Court has stated that Plaintiffs, at summary judgment, must adduce evidence satisfying a double-layered burden of proof in this case: First, Plaintiffs must survive summary judgment as to the substance of their EpiPen competition claims; and second, Plaintiffs must *then* survive summary judgment as to the elements of a securities fraud claim. At the motion to dismiss stage, the Court permitted these EpiPen competition claims to survive but held that Plaintiffs must demonstrate that Mylan actually did violate the Sherman Act as a necessary step to establishing their securities fraud claims. *See* MTD Op. II at 10.

2. Market Structure and Regulatory Background

The epinephrine market is highly complex. As the Tenth Circuit pointed out when considering facts very similar to those at issue here, "When antitrust and the health insurance industry meet, a *nearly* impenetrable fog descends upon what might otherwise be a manageable case." *In re EpiPen (Epinephrine Injection, USP) Marketing & Sales Practs. & Antitrust Litig.*, 44 F.4th 959, 1006 (10th Cir. 2022) (hereinafter "*EpiPen III*").

Mylan is a manufacturer of drugs, including the EpiPen. The challenged contracts in this case concern not how Mylan manufactures the EpiPen, but the chain of distribution that gets

prescriptions to individual patients. When an individual pays a price for a prescription, that "cost . . . is shared between the patient and [the] patient's health plan, so the amount a patient pays depends on the existence and extent of a patient's insurance." *EpiPen III* at 965. While the uninsured pay the list price at the pharmacy, the amount actually paid out of pocket by insured patients varies and is subject to continuing negotiation between that individual's health plan and a drug's manufacturers about what is known as the drug's "rebate rate." *Id.* This "rebate is, in effect, a price discount" paid by manufacturers like Mylan, and rebates, across all drugs, save billions of dollars, year over year, for the health plans – a crucial component of their profitability. *See id.* at 965–66.

There is another layer of contracting that is particularly essential for understanding Plaintiffs' allegations in this case. Health plans are generally owned by insurers. When patients select health plans, they do so based on what is known as that plan's "formulary" or the "list of drugs covered by the health plan." *Id.* at 966. Health plans are not required to cover all prescription drugs; some health plans contain broader formularies than others, and as most Americans know, this "choice comes at a cost." *Id.*

Managing a plan's formulary is central to the health plans' businesses, so health plans generally, though not universally, contract with Pharmacy Benefit Managers (PBMs) to manage them. As the Tenth Circuit put it:

> PBMs are effectively purchasing cooperatives. Instead of hundreds or thousands of health plans individually negotiating formulary access and rebates, the PBM acts in their collective interest, wielding the health plans' aggregate purchasing power to gain greater discounts than the health plans could obtain individually. After negotiating rebates with drug manufacturers, PBMs develop national formularies that health plans can adopt or customize in response to a particular plan's needs.

Id. at 966.

Plaintiffs' EpiPen competition claims in this case essentially rest on the following: Aspects of Mylan's negotiating with the PBMs are alleged to be either monopolistic or else significantly injurious to competition, such that when Mylan offered fairly vanilla statements to investors explaining its income and the place of its EpiPen product in the market (and assessing that the market was "competitive"), it materially misled them by failing to alert the reasonable investor that, in fact, Mylan's place in the epinephrine market and the resulting income were primarily sustained by antitrust violations.

3. Prior Litigation

The substantive issues related to Mylan's potential antitrust liability for marketing EpiPen have been the subject of a Multidistrict Litigation (MDL) in the District of Kansas before U.S. District Judge Daniel D. Crabtree, which has spawned two summary judgment rulings, one of which was not appealed, and the other of which has been affirmed by the Tenth Circuit. While the Court does rely on Judge Crabtree's thorough and comprehensive rulings, it does not assign those decisions claim- or issue-preclusive effect and none of the MDL opinions has precedential effect here. While the Court reaches all the necessary issues *de novo*, those opinions provide persuasive authority on a number of issues.

In both of the MDL court's summary judgment opinions, it ruled for Mylan. First, in *EpiPen I*, which was appealed the Tenth Circuit last year and unanimously affirmed, Judge Crabtree granted summary judgment in favor of Mylan on three claims raised by its rival, Sanofi. *See In re EpiPen (Epinephrine Injection, USP) Marketing, Sales Practs. & Antitrust Litig.*, 507 F. Supp. 3d 1289, 1300 (D. Kan. 2021) (Crabtree, J.) (hereinafter "*EpiPen I*"). *EpiPen I* rejected a Sherman Act Section 2 exclusive dealing claim similar to that asserted by Plaintiffs here. Judge Crabtree, in reaching this conclusion, applied the traditional Supreme Court doctrine under *Tampa Electric* to assess Mylan's exclusive dealing contracts under the rule of reason.

Judge Crabtree based most of his decision for Mylan on a simple (undisputed then and now) factual point: The PBMs, not Mylan, initiated the challenged activities, and the PBMs were Mylan's customers. The Tenth Circuit agreed with the district court that the regulatory architecture undergirding this area produced a "highly consolidated" industry. *EpiPen III*, at 966. That court further agreed with the district court's conclusion that the evidence in the record could support only a finding that Mylan's exclusive dealing contracts were manifestly procompetitive and resulted in a diminution of EpiPen's price for consumers. The Tenth Circuit emphasized that undisputed statements by PBM executives in the record showed that the PBMs themselves could have opted, would have opted, and *did* opt to contract with Mylan's competitors (specifically, with Sanofi for its epinephrine product, Auvi-Q) to diminish price. *EpiPen* I at 1363; *EpiPen* III at 980-85. Further, the Tenth Circuit regarded as well justified the district court's conclusion that Mylan's contracts were freely terminable by both parties and of such a short duration that they were well within the norm of acceptable exclusive dealing contracts under the federal antitrust laws. *See EpiPen* I at 1344 ("[T]he . . . record establishes that payors invoked these termination provisions and renegotiated rebate agreements annually and, sometimes, even more frequently . . . . Indeed, it is undisputed that Sanofi renegotiated its 2013 and 2014 formulary coverage with payors, and in some cases, achieved better coverage for Auvi-Q when it made stronger rebate offers."); *EpiPen* III at 990 ("The record supports only one conclusion: when Sanofi beat Mylan's prices it succeeded."); *id.* at 999 ("Contrary to [the plaintiffs'] assertions, exclusivity was nor forced upon PBMs; exclusivity was wielded by PBMs to push for more competitive pricing."). As to the question of exclusive effect, the Tenth Circuit was blunter than the district court, finding this to be a case where the "challenged conduct is . . . wholly devoid of any inference of exclusionary effect." *EpiPen III*, at 991.

In *EpiPen II*, the MDL court dealt with the antitrust issue in a different posture: it considered a national consumer class action raising state-law conspiracy claims based on injuries to competition and, ultimately, bottom-line EpiPen price. *See In re EpiPen (Epinephrine Injection, USP) Marketing, Sales Practs. & Antitrust Litig.*, 545 F. Supp. 3d 922, 1008 (D. Kan. 2021) (Crabtree, J.) (hereinafter "*EpiPen II*"). Importantly, however, the district court, on consent of both Mylan and the MDL class counsel, issued its opinion in *EpiPen II* applying the precedent and principles of federal Sherman Act Section 1 case law to provide a unified conspiracy standard, and to minimize any state-law differences in doctrine. *EpiPen II* specifically held that it did not need to reach the issue of whether the price-cost test controlled, because even under the plaintiffs' proposed standard, their claim failed: First, the court could locate no record evidence of "coercion." *Id.* at 1005. Second, the court made the same findings as to duration and terminability as in the context of the Section 2 claims, and the court held that this made any injury to consumers or competition as a whole nonexistent. *Id.* at 1008-10. Last, the court held that there was simply no evidence of market foreclosure, let alone "substantial" market foreclosure, because "Mylan's rebate contracts were short in duration and easily terminable," and because it was "also undisputed that payors renegotiated contracts" with all relevant industry players, including Mylan, such that there was essentially no market effect fairly traceable to the challenged conduct, under either Section 1 or Section 2. *Id.* The MDL court noted that a showing of substantial foreclosure, for Section 1, would require Mylan to foreclose at least 30% of the market, which was patently unsupported. But the court did not rest only on this holding, considering qualitative plus other factors more pertinent to substantial foreclosure analysis in federal Section 2 cases, rejecting each of these arguments on their own terms.

B. Analysis

1. Section 2 Exclusive Dealing Claim

The Court begins with the Section 2 claims.

a. Substantive Antitrust Law

Under Section 2, it is illegal to "monopolize, or attempt to monopolize . . . any part of the trade or commerce among the several states." 15 U.S.C. § 2. Section 2 has two elements: monopoly and substantial foreclosure of competition. With respect to exclusive dealing agreements, the Supreme Court has long held that such agreements, whether challenged under Section 1 or Section 2, are presumptively procompetitive and lawful "unless the court believes it probable that performance of the contract will foreclose competition in a substantial share of the market." *Tampa Elec. Co. v. Nashville Coal Co*., 365 U.S. 320, 327 (1961).

To assess exclusive dealing contracts, courts apply the rule of reason. *See Jefferson Parish Hosp. Dist. No. 2 v. Hyde*, 466 U.S. 2, 44-45 (1984) (O'Connor, J., concurring in the judgment) (citing *Tampa Electric*, 365 U.S. at 333-35). This requires a "fact-specific assessment of 'market power and market structure to assess the challenged restraint's actual effect' on competition." *Ohio v. American Express Co.*, 138 S.Ct. 2274, 2283-84 (2018) (quoting *Copperweld Corp. v. Independence Tube Corp*., 467 U.S. 757, 768 (1984)).

There are certain factual bases that must be satisfied to challenge an exclusive dealing contract. Under either Section 1 or Section 2, it is required that plaintiffs "present strong evidence" not just of effect but, specifically of substantial market foreclosure. *See A.V.E.L.A., Inc. v. Est. of Marilyn Monroe, LLC*, 241 F. Supp. 3d 461, 488 (S.D.N.Y. 2017) (citing *Sell It Social, LLC v. Acumen Brands, Inc*., 2015 WL 1345927, at *5 (S.D.N.Y. March 13, 2017)); *Xerox Corp. v. Media Sci. Intern., Inc*., 511 F. Supp. 2d 372, 389 (S.D.N.Y. 2007). "Summary judgment in exclusive dealing cases is appropriate when a plaintiff fails to offer evidence that

exclusive agreements foreclosed a large enough share of the market to raise a reasonable inference that the agreements harmed competition." *Mazda v. Carfax, Inc.*, 2016 WL 7231941, at *11 (Dec. 9, 2016) (Nathan, J.) (citing *Discover Fin. Servs. v. Visa U.S.A. Inc.*, 598 F. Supp. 394, 406 (S.D.N.Y. 2008)), *aff'd*, 726 Fed. App'x 66 (2d Cir. 2018).

Like the MDL court, this Court concludes that the record is insufficient to permit a reasonable juror to conclude there was substantial foreclosure. "When considering whether [a] . . . contract . . . tended to foreclose a substantial volume of competition" in *Tampa Electric*, the Supreme Court considered factors including "whether the market includes a seller with a dominant position, whether the market has 'myriad outlets with substantial sales volume,' the prevalence of exclusive contracts in the industry, the duration of the contract, and any pro-competitive justifications for the contract." *EpiPen I* at 1005 (citing *Tampa Elec.*, 365 U.S. at 334–35). The Third Circuit applied *Tampa Electric* to a medical rebate context similar to this one in *Z.F. Meritor v. Eaton Corporation*. Combining *Tampa Electric* and *Z.F. Meritor*, Judge Crabtree summarized the relevant factors as: (1) whether the defendant has significant market power; (2) whether there is substantial market foreclosure; (3) whether the contract's duration is sufficient to prevent meaningful competition by rivals; (4) an analysis of likely or actual anticompetitive effects considered in light of any procompetitive effects; (5) whether the defendant engaged in coercive behavior; and (7) the use of exclusive dealing by competitors of the defendant. *EpiPen I* at 1004 (citing *Z.F. Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 271-72 (3d Cir. 2012)).

Plaintiffs fail to establish a sufficiently substantial impact on competition. First, Plaintiffs concede that, at the very most, Auvi-Q was "not covered" only for 19% of privately insured patients in Q3 2014, 29% in Q3 2014, and 16% in Q3 215, and that, by 2015, Auvi-Q

had 80% acceptance overall. This is not substantial foreclosure under any standard. And there is no evidence in the record to support any coercion. Moreover, Plaintiffs concede by silence that these contracts were generally pro-competitive. And the novel expert testimony that Plaintiffs adduce here — that of Dr. Ingberman — is stronger for Defendants than Plaintiffs, because even Dr. Ingberman acknowledged the factual reality that the PBMs could and did use the PBM contracts' short duration and easy terminability to renegotiate key terms and generate competition between Sanofi and Mylan — all because the PBMs were obviously "prepared to exclude EpiPen," the source of their leverage.[3] (Ex. 9 (EAI Rpt.) ¶ 329 n. 379.)

Plaintiffs' remaining argument — that Mylan increased the price of the EpiPen during the relevant period — is by itself insufficient to establish a Section 2 claim because "high prices, far from damaging competition, invite new competitors into [a] monopolized market." *See Berkey Photo, Inc. v. Eastman Kodak Co.*, 603 F.2d 263, 274 n. 12 (2d Cir. 1979). And the record bears this out: The evidence supports the inference that once Sanofi decided to compete directly on price, they experienced significant market penetration. Indeed, price plummeted for both the EpiPen and Auvi-Q "in late 2014 and early 2015, when Sanofi began competing more aggressively . . . by offering greater rebates on Auvi-Q in exchange for better formulary placement." *EpiPen* I at 1365. Accordingly, "no reasonable jury could conclude that Mylan's . . . [PBM] agreements increased EpiPen's prices" because, in fact, the record shows that "Mylan's rebate offers caused EpiPen prices to *drop* when Sanofi competed against Mylan based

[3] For purposes of this motion, the Court accepts that Dr. Ingberman's Report on EpiPen would be admissible at trial, considers its findings, and holds that it is not sufficient to overcome the other legal defects in Plaintiffs' claims. Defendant's motion to exclude Dr. Ingberman's report is thus denied as moot. (ECF No. 371.) Because the Court does not rely on any expert testimony proffered by Defendants and objected to by Plaintiffs in this opinion, it also denies Plaintiffs' motions to exclude Defendants' EpiPen competition experts as similarly moot.

on price." *Id.* (emphasis in original). Indeed, "the summary judgment facts don't present a triable issue of foreclosure when it is undisputed that Auvi-Q had access to 80% of the commercial market within two years of its coming to the [epinephrine] market." *EpiPen I* at 1355.

The core insight of the MDL opinions is that the PBMs, Mylan's *own customers*, exercise significant agency throughout this sector and appear responsible for the exclusive dealing nature of these contracts. "In a case like this where [PBMs] instigated exclusivity to obtain lower prices [rather than its having been imposed by Mylan], . . . [a] plaintiff must show two things to prove the exclusive dealing agreement is anticompetitive." *EpiPen III*, at 986. First, a challenger "must show that the agreements are likely to foreclose it from doing business in the relevant market." *EpiPen III* at 986 (citing *Tampa Elec.*, 365 U.S. at 334; *Roland Mach. Co. v. Dresser Indus., Inc.*, 749 F.2d 380, 394 (7th Cir. 1984) (Posner, J.)). And second, a plaintiff "must show that once foreclosed, the defendant could reduce output or increase prices and those consumer harms would outweigh any consumer benefit received from the period of lower sales." *EpiPen III*, at 9866 (citing *Roland*, 749 F.2d at 394; *United States v. Microsoft Corp.*, 253 F.3d 34, 58-59 (D.C. Cir. 2001); *Novell, Inc. v. Microsoft Corp.*, 731 F.3d 1064, 1075 (10th Cir. 2013); *Barry Wright Corp. v. ITT Grinnell Corp.*, 724 F.2d 227, 237 (1st Cir. 1983)).

These requirements are proper articulations of the requirements of Section 2 in this highly regulated industry and are in keeping with Second Circuit precedent. The MDL court, moreover, explains the evidentiary showing necessary to survive a summary judgment motion on an exclusive dealing suit in this industry. On both prongs, Plaintiffs scarcely cite the record, instead relying on technical legal pivots to differentiate their claims here from those in the MDL. But there is not enough here. The view that Mylan was aggressively competing rather than

impeding competition is essentially confirmed by parts of Dr. Ingberman's deposition. Dr. Ingberman explained that in a hypothetical competitive world, Mylan, but not Sanofi, would be required to refrain from any PBM contracts that named competitors specifically; PBMs could freely seek out rebates conditioned on exclusivity, but only Sanofi could enter this contract. (Ex. 10 (EAI Tr.) 74:9-75:6.)

b. Scienter

To survive summary judgment as to allegedly misleading statements related to EpiPen's competitive marketing, Plaintiffs must show, first, a Sherman Act violation and, second, that the violation, if proven, was suppressed with scienter. *See* MTD Op. II at 10. To survive summary judgment on securities fraud claims under Section 10(b) and Rule 10b-5, a plaintiff must evince sufficient evidence that there is a reasonable factual basis for a jury to conclude "that the defendant made a false statement or omitted a material fact, with scienter, and that plaintiff's reliance on defendant's action caused plaintiff injury." *Kalnit v. Eichler*, 264 F.3d 131, 137-38 (2d Cir. 2001) (quoting *San Leandro Emergency Med. Group Profit Sharing Plan v. Philip Morris Cos*., 75 F.3d 801, 808 (2d Cir.1996)) (citing *In re Time Warner Inc. Secs. Litig*., 9 F.3d 259, 264 (2d Cir.1993)). The Private Securities Litigation Reform Act of 1995 (PSLRA) requires that state of mind be proven as an element for each and every allegedly misleading statement under the securities laws. *See* 15 U.S.C. § 78(u)-4(b)(2).

To satisfy the scienter requirement, plaintiffs have two options. First, the plaintiff may choose to adduce specific facts demonstrating that the "defendants had both a motive and opportunity to commit fraud." *Kalnit*, 2164 F.3d at 138. Alternatively, the plaintiff can produce "facts that constitute strong circumstantial evidence of conscious misbehavior or recklessness." *Id.* (quoting *Acito v. IMCERA Grp., Inc.*, 47 F.3d 47, 52 (2d Cir. 1995)).

Plaintiffs forego developing arguments that the Defendants engaged in willful and knowing misrepresentation. Therefore, they must satisfy the requirements of the second pathway and provide "strong" circumstantial evidence of conscious misbehavior or recklessness.

In order to show securities fraud by recklessness, a plaintiff bears the following burden:

> . . . . . [U]nder the "conscious misbehavior" theory, the [plaintiffs] must show that they alleged reckless conduct by the [defendants], which is, "at the least, conduct which is highly unreasonable and which represents an extreme departure from the standards of ordinary care to the extent that the danger was either known to the defendant or so obvious that the defendant must have been aware of it."

In re Carter-Wallace Secs. Litig., 220 F.3d 36, 39 (2d Cir. 2000) (quoting *Rolf v. Blyth, Eastman Dillon & Co.*, 570 F.2d 38, 47 (2d Cir. 1978)). Plaintiffs are correct when they refer to the Second Circuit's *Novak* opinion as suggesting that "[w]here Defendants 'knew facts or had access to information suggesting that their public statements were not accurate,' there [can be] a 'strong inference of scienter.'" (P. Memo. at 29 (quoting *Novak*, 216 F.3d at 311).) But in context, this quoted line is a fact-specific holding about the adequacy of the *Novak* complaint, one sustained by facts that are readily distinguishable from the case here.[4] As this Court previously stated, "[r]ecklessness is defined as 'at least . . . an extreme departure from the standards of ordinary care . . . to the extent that the danger was either known to the defendant or so obvious that the defendant must have been aware of it." MTD Op. I at 21 (quoting *ECA, Local 134 IBEW Joint Pension Tr. of Chi. v. J.P. Morgan Chase Co.*, 553 F.3d 187, 198 (2d Cir. 2009)).[5]

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[4] Unlike here, in *Novak* there was evidence of the personal and corporate defendants willfully concealing their actions from investors, *Novak*, 216 F.3d, at 311; corporate knowledge that their inventory was wholly useless for the purposes of selling the goods currently held by defendant corporation, *id.* at 311 – 12; and extensive evidence that defendants adopted procedures in violation of their own corporate bylaws to cover up misconduct, *id.* at 312

[5] In *Kalnit*, the Second Circuit read *Novak* as holding that "[m]otives that are generally possessed by most corporate directors and officers do not suffice; instead, plaintiffs must assert a

That a defendant violated a law or industry practice, even if clearly shown, is not sufficient to support an inference of scienter by gross negligence. Not just any failure to "see the obvious" suffices to sustain scienter; rather, there must be an "egregious refusal to see the obvious." *Novak,* 216 F.3d at 208 (quoting *Chill*, 101 F.3d at 269). Proof of "repeated violations of [a liability standard] is not, by itself, sufficient to [demonstrate] conscious misbehavior" as a plaintiff must also show a mental state of extreme recklessness if not actual knowledge. *Funke*, 237 F.2d at 468; *cf. Chill v. Gen. Electric Co.*, 101 F.3d 263, 270 (2d Cir. 1996) ("Allegations of a violation of [accepted accounting practices] or SEC regulations, without corresponding fraudulent intent, are not sufficient to state a securities fraud claim."). In addition, plaintiffs must adduce facts providing a basis to conclude that a defendant's conduct to be "'highly unreasonable,' representing an 'extreme departure from the standards of ordinary care . . . to the extent that the danger was either known to the defendant or so obvious that the defendant must have been aware of it." *Novak*, 216 F.3d at 398 (quoting *Rolf,* 570 F.2d at 47).

Turning to Plaintiffs' securities fraud claim premised on an underlying exclusive dealing violation of Section 2, this claim fails for lack of scienter, even if Plaintiffs had a stronger case on the substantive antitrust portion of their claim. Overlaying the MDL court's analysis with the elevated pleading requirements for securities fraud plaintiffs provides an even more compelling reason that Plaintiffs' claim fails. Plaintiffs' burden here is to show a genuine issue of material fact as to whether, when Mylan made statements generally describing EpiPen's market sector as

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concrete and personal benefit to the individual defendants resulting from fraud." *Kalnit*, 264 F.3d, at 139 (citing *Novak*, 216 F.3d at 307). Facts showing "that defendants wanted the corporation to appear profitable or sought to keep stock prices high are insufficient" for scienter; facts showing "the defendants sought to inflate the market price while they sold their own shares would suffice." *Funke v. Life Financial Corp*., 237 F. Supp. 2d 458, 467 (S.D.N.Y. 2002) (citing *Kalnit*, 264 F.3d at 139, 140; *Novak*, 216 F.3d at 307, 307-08, 307-09, 308; *Chill v. Gen. Electric Co.*, 101 F.3d 263, 267 (2d Cir. 1995); *San Leandro*, 75 F.3d at 814; *Acito*, 47 F.3d at 54))).

competitive, Mylan either knew or unequivocally should have known that Mylan was engaged in an antitrust conspiracy to defraud consumers, hospitals, and pharmacies. With the benefit of hindsight and a factual record developed over years of litigation, four federal judges have concluded that there is no reasonable basis to conclude that a Section 2 exclusive dealing violation occurred. No reasonable factfinder could conclude that the Defendants could have known that they engaged in such a conspiracy at the time of the challenged statements absent some sort of evidence that Plaintiffs have failed to adduce.

The highly generic nature of the statements at issue – none specific to EpiPen – give rise to an elevated burden in adducing "specific information" that would contradict those statements in a manner supporting scienter by conduct. This is a fatal flaw, applicable to all three of the EpiPen competition claims raised by Plaintiffs. *See S.E.C. v. Yorkville Advisors, LLC*, 305 F. Supp. 3d 486, 512 (S.D.N.Y. 2018) (requiring "specific information" that contradicts the challenged statements to assume a defendant would have had scienter as to the contradiction). At most, Plaintiffs have some evidence of Mylan being too optimistic. But the "fact that management's optimism about a prosperous future turned out to be unwarranted is *not circumstantial evidence* of conscious . . . recklessness." *Rothman*, 220 F.3d at 90 (citing *Shields v. Citytrust Bancorp, Inc.*, 25 F.3d 1124, 1129 (2d Cir. 1994)); *see also Stevelman v. Alias Research, Inc.*, 174 F.3d 79, 85 (2d Cir. 1999) (gathering cases).

The Court concludes that no reasonable juror could find that Mylan consciously or recklessly misled shareholders about its own self-perception of compliance with the antitrust laws.

2. Section 2 Bribery Claim

At the summary judgment stage, Plaintiffs reframe part of their Section 2 argument as one premised on commercial bribery, alleging that Mylan's PBM contracts amounted to illicit

kickback schemes or bribes. (*See* P. Memo. at 22 – 25.) This, according to Plaintiffs, alleviates their burden of showing substantial foreclosure and, more importantly, amounts to an entirely distinct theory of Section 2 liability that sidesteps the problems that the MDL court identified with the exclusive dealing theory.

c. Substantive Antitrust Standard

It is not self-evident, and Plaintiffs cite no authority suggesting, that the challenged contracts are not still exclusive dealing contracts and so still entitled to the presumption of being pro-competitive. A contract does not cease being a presumptively pro-competitive exclusive dealing contract simply because of a new label. (*See* ECF No. 341, at 12). Since the challenged contracts are still exclusive dealing contracts (and specifically exclusive dealing contracts that the Court has concluded have pro-competitive effects), any other Section 2 claim brought by a rival or consumer would fail to involve a judicially recognizable injury under the antitrust laws because at all relevant times, "customers remain[ed] free to switch to a different product [from EpiPen] in the marketplace." *EpiPen II* at 1008. The injury showing is a requirement for winning any sort of antitrust suit. *See Bustop Shelters, Inc. v. Convenience & Safety Corp.*, 521 F.Supp. 989, 997 (S.D.N.Y. 1981) ("Whatever the theory, an antirust injury must be alleged. And antitrust injury is injury to competition generally, not injury to one competitor.") (quoting *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 488 (1977)); *accord Schiller v. Duthie*, 2017 WL 3726993 at *13 (S.D.N.Y. Aug. 28, 2017) ("The injury . . . (lost [revenues]) did not flow from that which makes the alleged conduct illegal . . . but rather from the decisions of municipalities—for reasons of ignorance, cronyism or otherwise—to contract through [a

corrupt program] despite the fact that [the program] was allegedly disserving its municipal clients." (internal citations omitted)).[6]

This is a specific requirement for Section 2 commercial bribery claims. *Doron Precision Systems, Inc. v. FAAC Inc*., 423 F.Supp.2d 137, 185 (S.D.N.Y. 2006) ("Late courts faced with Sherman Act claims—both Sections 1 and 2—based on similar conduct . . . . have held that" for a kickback or bribery scheme to be actionable under the Sherman Act, the plaintiff must show the scheme "endanger[ed] the competitive process" by demonstrating that the effect was to deny "the ultimate purchaser . . . a choice." (quoting *Triple M. Roofing Corp. v. Tremco, Inc*., 753 F.2d 242, 247 (2d Cir. 1985))). That is, when bribery is offered to support a Sherman Act claim, the correct inquiry is "not whether the defendant's practices were unfair or tortious, but whether those practices hobbled competition." *Doron*, 423 F.2d at 185 (quoting *Richard Hoffman Corp. v. Integrated Bldg. Sys*., 610 F. Supp. 19, 22 n. 3 (N.D. Ill. 1985) (internal quotations marks omitted). If there is insufficient evidence to conclude there was overall harm to competition, that may logically spell the end of any claim. *See supra* II.B.1.

But assuming *arguendo* that Plaintiffs have met that burden, they are not out of the woods. Summary judgment on the bribery claim is warranted because no reasonable juror could

[6] This creates an either-or. *Either* the challenges to the same set of PBM contracts articulated as a Section 2 commercial bribery claim and, in later, as a Section 1 vertical constraint claim are semantic: These were output-based contracts that were, on net, pro-competitive, *see supra* II.B.1.A, *or* the price-cost test applies to the second and third claims because price predominates, and the two additional claims fail. In this circuit, price is said to predominate, and so courts must apply the price-cost test, when the plaintiff's claim amounts to "the deliberate sacrifice of present revenues for the purpose of driving rivals out of the market and then recouping the losses through higher profits earned in the absence of competition." *Northeastern Tel. Co. v. American Tel. & Tel. Co*., 651 F.2d 76, 86 (2d Cir. 1981). Provided that price predominates, Plaintiffs concede that Mylan at all times priced EpiPen below cost, and precedent requires dismissal of the latter two claims under rule of reason analysis. *See Eisai, Inc. v. Sanofi-Aventis U.S., LLC*, 2014 WL 1343254, at *25–*26 (D.N.J. March 28, 2014) (gathering cases and explaining the purpose of this rule).

conclude that there was sufficient evidence to meet the anticompetitive conduct requirement with respect to alleged bribes or kickbacks. To state a Section 2 claim for bribery, plaintiffs must make a *prima facie* case of commercial bribery. "The Second Circuit has never reached the question of whether—and under what circumstances—commercial bribery can form the basis of a claim under § 2(c). . . . [But] [e]ven assuming that a § 2[] claim could be based on commercial bribery, a necessary requirement for stating such a claim would be allegations sufficient to establish commercial bribery." *Blue Tree Hotels Inv. (Canada), Ltd. v. Starwood Hotels & Resorts Worldwide, Inc*., 369 F.3d 212, 221 (2d Cir. 2004) (citing *Excel Handbag Co. v. Edison Bros. Stores, Inc.*, 630 F.2d 379, 387-88 (5th Cir. 1980)); *accord Instructional Sys. Development Corp. v. Aetna Cas. Sur. Co*., 817 F.2d 639, 649 (10th Cir. 1987).

There is clearly insufficient evidence to sustain a commercial bribery antitrust claim under Second Circuit precedent. In *Blue Tree Hotels*, the court held that sufficient evidence to allege a claim, let alone survive at summary judgment, could not be premised on mere "tautology." *Id*. at 221. Plaintiffs have not made the claim, much less provided evidence, that the individual payments to PBMs were per se "improper." Plaintiffs have neither alleged nor proven "facts constituting commercial bribery." *Id*. at 222-23. As Defendants point out, throughout multiple iterations in various federal and state courts, "Plaintiffs did not ask a single deposition question about bribery, collusive vertical restraints or violations of federal or state anti-bribery laws." (ECF No. 341 ("D. Reply") at 8.)

The same result as in *Blue Trees Hotels* is justified here. Like the plaintiffs there, Plaintiffs here "contend that [Mylan] and its [PBM contractors] engaged in a 'Kickback Scheme' that constituted commercial bribery. This claim . . . is premised entirely on tautology created by the fact that [Plaintiffs] have labeled [all] payments to the [PBMs] 'Kickbacks': because the

[PBMs] pay kickbacks to [Mylan], they are engaged in commercial bribery, and because the parties are engaged in commercial bribery, the payments made by [Mylan] are kickbacks." *Blue Tree Hotels*, 369 F.3d at 221. These are conclusory and tautological assertions bundled under the heading of Section 2 bribery, and they fail to survive summary judgment for the same reasons.

There is a third independent reason that the commercial bribery claim fails. In addition to the wrongful conduct element, to state a commercial robbery claim, plaintiffs must further show (1) motive; (2) inducement; and (3) a violation of the payees' preexisting fiduciary duties. Plaintiffs make three arguments on this point, none of which is persuasive. First, Plaintiffs argue that the rebate payments to the PBMs were no ordinary business dealing but, rather, solely intended to induce the PBMs to give up their role in disciplining price for health care consumers. (P. Memo. at 38 – 39.) But this is unsubstantiated, even in Dr. Ingberman's report. That document provides no citations to any evidence for the view that Mylan's main motive was to vitiate competition besides a conclusory statement, and it is the only authority cited by Plaintiffs on this point. This has no bearing on inducement of the PBMs (which are not discussed in this part of Plaintiff's brief), nor does it elucidate why the challenged PBM contracts would cause those PBMs to violate some external fiduciary duty.

Plaintiffs also argue that Mylan's motive was one of responding to the threat of "competition" from Sanofi's Auvi-Q.[7] (P. Memo. at 39.) The only evidence that could sustain

[7] This factual claim also lacks support in the record. To support it, Plaintiffs do not cite the factual record, but, rather, refer to a Rule 12(b)(6) opinion issued in yet another parallel EpiPen antitrust lawsuit, this one before Judge Docherty in the District of Minnesota, which cannot evidence their assertion. The district court merely denied Mylan's motion to dismiss on a similar bribery claim under Section 2 on the basis that the allegations in the plaintiff's complaint, taken as true, would state a claim. *See In re EpiPen Direct Purchaser Litig.*, 2021 WL 147166 at *24-25 (D. Minn. Jan. 15, 2021).

Plaintiffs past summary judgment is Dr. Ingberman's opinion that the PBMs "acquiesced" to increased payments, which, at least in their motion in limine on this issue, Plaintiffs interpret to imply some form of coercion or illicit payment. (*See* ECF No. 414 at 16.) This is unpersuasive. First, this is a standalone sentence in Dr. Ingberman's report; it is an ambiguous statement that Dr. Ingberman did not elaborate on which alone would not be enough to survive summary judgment. Even if this statement in isolation were as potent as Plaintiffs say, Plaintiffs themselves disavowed that it amounted to evidence of either Mylan's or the PBMs' mental state. (*See id.* (rejecting Defendants' argument that Ingberman here opined on Mylan's or the PBMs' mental state and construing the statement as one that "cannot fairly be read as an attempt at mind-reading" but rather only amounts to his "opin[ing] that the PBMs had an economic incentive to acquiesce").

Third, Plaintiffs argue that the Court should deny summary judgment on the bribery claim because "Mylan retained a stable market share despite price increases." (P. Memo. at 40.) Again, while it is possible to imagine how this might be probative, for example, of an underlying monopolization element, it does not bear on whether there is sufficient evidence in the record that Mylan engaged in bribery.

Plaintiffs do not identify any act of illegality that they claim constituted unlawful bribery, which raises their burden to survive summary judgment on a claim like this – one which require some showing of predicate illegal actions. In the absence of direct evidence or a developed record to establish this claim circumstantially, Plaintiffs' argument here amounts to mere speculation that Mylan "would have decreased its prices but for the conspiracy. But this amounts to little more than speculation" and is insufficient to survive summary judgment. *MacDermid Printing Solutions LLC v. Cortron Corp.*, 833 F.3d 172, 184 (2d Cir. 2016).

d. Application of Scienter

Like the exclusive dealing claim, all the above analysis provides still another reason that Plaintiffs' claims cannot survive summary judgment: Plaintiffs fail to show a genuine issue of fact as to scienter related to the bribery allegations. This analysis is substantially the same as above, with one addition. Plaintiffs do not contest the MDL court's holding, reiterated by Defendants here, that the entirety of Mylan's PBM course of dealing, including the payment of excess rebate rates, was an industry standard and "normal competitive tool within the [EAI] market." *EpiPen II* at *68, *71. That alone precludes a basis for finding scienter on a Section 2 claim premised on unproven, allegedly predicate illegal conduct; it dispels any inference that Defendants knew or should have known that this model of contracting amounted to bribery.

Because the open use of these agreements throughout the industry "renders implausible any inference that [Defendants] knew the [PBM] agreements were illegal, or, more to the point, knew that the disclosures that are the subject of the complaint were likely fraudulent," there is no evidence in the record sufficient to permit a reasonable juror to conclude that Defendants knowingly, or grossly recklessly, made materially misleading statements regarding the competitiveness of EpiPen's market based on secret knowledge of predicate unlawful conduct. *See In re Axis Capital Hldgs. Ltd. Sec. Litig.*, 456 F. Supp. 2d 576, 592 (S.D.N.Y. 2006) (citing *In re Bristol-Myers Squibb Sec. Litig.*, 312 F. Supp. 2d. 549, 567-68 (S.D.N.Y. 2004)) (holding that an otherwise unlawful accounting technique could not be the basis of a securities fraud claim because its status as industry standard precluded any inference of recklessness, let alone knowledge); *Funk v. LifeFin Corp.*, 237 F. Supp. 2d 458, 468-69 (S.D.N.Y. 2002) (same)).

3. Section 1 Vertical Restraint Claim

Plaintiffs' second major pivot is toward Section 1 and away from Section 2. The Court assumes without concluding that the elements of a Section 1 claim were sufficiently pleaded to

avoid dismissing this line of argument entirely as untimely. That said, this claim, and the evidence supporting it, is far less developed than Plaintiffs' exclusive dealing claim. For example, at oral argument, the Plaintiffs clarified for the first time important ambiguities about the nature of their Section 1 claim, and the Court relies on these statements. First, Plaintiffs clarified that the entirety of their Section 1 claim was based on an alleged antitrust injury sounding only in price. (*See* ECF No. 458 ("Oral Arg.") at 21 (explaining that the elements of the Section 1 claim rested entirely on showing that Defendants' dealings with the PBMs amounted to an "unreasonable restraint of trade in the form of increased prices in the EAI market as a whole").) Second, despite ambiguous language on this point in Plaintiffs' papers, Plaintiffs clarified that the factual allegations and evidence surrounding the alleged kickback scheme are "neither here nor there" in this context, because "[k]ickbacks . . . are not a part of the section 1 claim. . . . [T]he two elements are contracts and increased net prices." (*Id.* at 34.)

e. Substantive Antitrust Law

Section 1 of the "Sherman Act prohibits '[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce.'" *In re Keurig Green Mountain Single-Serve Coffee Antitrust Litig.*, 383 F.Supp.3d 187, 241 (S.D.N.Y. 2019) (quoting 15 U.S.C. § 1 (internal quotation marks omitted)). "Contracts that foreclose competition in a 'substantial share' of the market may be unlawful under Section One of the Sherman Act." *Dial Corp. v. News Corp.*, 165 F. Supp. 3d 25, 33 (S.D.N.Y. 2016) (Pauley, J.) (quoting *Tampa Elec. Co.*, 365 U.S. at 327). "Exclusive dealing violates the law when it has the effect of raising rivals' costs by foreclosing efficient means of distribution to actual or potential competitors." *Keurig*, 383 F.Supp.3d at 239 (citation omitted).

"[A] plaintiff claiming a § 1 violation must first establish a combination or some form of concerted action between at least two legally distinct economic entities." *Capital Imaging Assocs., P.C. v. Mohawk Valley Med. Assocs., Inc*., 996 F.2d 537, 542 (2d Cir. 1993). "If a § 1 plaintiff establishes the existence of an illegal contract or combination, it must then proceed to demonstrate that the agreement constituted an unreasonable restraint of trade either per se or under the rule of reason." *Id*. Typically, a Section 1 case will turn on adducing evidence of conspiracy (the first element) that is sufficiently tied to the challenged conduct (the second element). "The crucial question in a Section 1 case is therefore whether the challenged conduct 'stems from independent decision or from an agreement, tacit or express.'" *Mayor & City Council of Baltimore v. Citigroup, Inc.*, 709 F.3d 129, 136 (2d Cir. 2013) (quoting *Starr v. Sony BMG Music Entm't*, 592 F.3d 314, 321 (2d Cir. 2010); *Theatre Enters., Inc. v. Paramount Film Distrib. Corp*., 346 U.S. 537, 540 (1954)).

Section 1 claims require adducing proof in excess of Section 2 claims for reasons of logic and statutory construction. As the Third Circuit has explained, "[u]nlike § 2 of the Sherman Act, which addresses monopolization and other illegal unilateral conduct, § 1 only applies when there is an agreement to restrain trade; a single firm's independent action, no matter how anticompetitive its aim, does not implicate § 1." *Valspar Corp. v. E.I. Du Pont de Nemours & Co*., 873 F.3d 185, 191 (3d Cir. 2017) (citing *Monsanto*, 465 U.S. at 761).

"Under § 1 of the Sherman Act, the [horizontal restraints on trade] are, with limited exceptions, per se unlawful, while [vertical restraints on trade] are unlawful only if an assessment of market effects, known as a rule-of-reason analysis, reveals that they unreasonably restrain trade." *United States v. Apple*, 791 F.3d 290, 313-14 (2d Cir. 2015) (citing *Leegin Creative Leather Prods., Inc. v. PSKS, Inc*., 551 U.S. 877, 893 (2007). Here, neither side claims

the Section 1 violation would be subject to *per se* analysis, and each agrees that the Court should apply the rule of reason in assessing the second element of the Section 1 claim. The "rule of reason" is the standard for whether restraints not unlawful *per se* nonetheless violate Section 1. *See Leegin,* 551 U.S. at 885–86.

Applying the rule of reason, the Court holds that no reasonable juror could find a violation of Section 1 based on Mylan's use of exclusive dealing contracts with PBMs.

The "purpose of a rule of reason analysis is to enable a finder of fact to first determine whether a restraint imposes an unreasonable restraint on competition." *See In re Aluminum Warehouse Antitrust Litig.*, 2014 WL 4277510 at *25 (S.D.N.Y. August 29, 2014) (citing *State Oil v. Khan*, 522 U.S. 3, 10 (1997); *Paycom Billing Servs. v. Mastercard Intern., Inc.*, 467 F.3d 283, 289–90 (2d Cir. 2006)). The inquiry, then, is a way for courts to answer the question of ultimate harm to competition and distinguish it from other, presumptively legal (and presumptively pro-competitive) business practices.[8]

As a threshold matter, a plaintiff must adduce facts that would permit a reasonable juror to conclude that "existence of a combination that causes an unreasonable restraint of trade." *Id.* at *25. According to the Second Circuit,

> A plaintiff seeking to prove an antitrust violation under the rule of reason must initially show that the challenged action adversely affected competition in the relevant market. . . . A plaintiff may satisfy this requirement in either of two ways. First, a plaintiff may offer direct evidence of harm to competition by proving higher prices, reduced output, or lower quality in the market as a whole.

[8] The rule of reason is a three-step burden-shifting test. Initially, the "plaintiff must allege the plausible existence of a combination that causes an unreasonable restraint of trade." *Aluminum Warehouse,* 2014 WL 4277510 at *25. Assuming plaintiff does so, then "[t]he burden shifts to defendant to present the procompetitive value of the practice." *Id*. And third, "if defendant carries that burden, then the burden shifts back to plaintiff, who must show that the same procompetitive effect could have been achieved by less restrictive means." *Id*. (citing *Virgin Atl. Airways Ltd., v. British Airways PLC*, 257 F.3d 256, 264 (2d Cir. 2001)).

> Alternatively, a plaintiff may demonstrate an adverse effect indirectly by establishing that the alleged conspirators had sufficient 'market power' to cause an adverse effect, 'plus some other ground for believing that the challenged behavior' has harmed competition.

MacDermid, 833 F.3d at 182.

Plaintiffs assert that arguments regarding substantial foreclosure are irrelevant to the class's Section 1 claim because "the claim does not depend on any act of exclusion and so does not require any showing of market foreclosure or below-cost pricing." (P. Memo. at 35–36.) Similarly, Plaintiffs' counsel, at oral argument, stated, "The District of Kansas said nothing whatsoever about section 1 of the Sherman Act. That is an irrelevant opinion with regard to this theory of the case." (Oral Arg. at 21.)

This statement is contradicted by the MDL court's opinions. The MDL court explicitly dealt with the issue of Section 1 as a consumer class action claim, writing in *EpiPen II*:

> Although plaintiffs assert their antitrust claims under particular state laws, they ask the court to evaluate them "under the same legal standards as Sherman Act Section One (Conspiracy)" and "Sherman Act Section Two (Monopolization)[.]" . . . . Defendants agree for "the purpose of summary judgment." . . . So, consistent with the parties' agreement, the court evaluates plaintiffs' antitrust claims on summary judgment under the legal standards that apply to the Sherman Act.

545 F. Supp. 3d 922, 981 n.52 (D. Kan. 2021). The MDL court indicated that its combined decisions in the consumer class and competitor plaintiff cases would resolve all questions of legality of the exclusive dealing rebate agreements under any part of the Sherman Act. *Id.* at 1003 n. 58 (noting that this opinion focused on the common element of whether there was "anticompetitive conduct," a common necessary showing for sections 1 and 2 of the Sherman Act and noting that the Supreme Court's decision in *Tampa Electric* made this exact move shifting between Clayton Act claims and section 1 claim. This was appropriate, the MDL court held, because "each statute include[s] an anticompetitive conduct element, although each statute

articulates that element in a slightly different way." (quoting *Z.F. Meritor*, 696 F.3d at 269 n.9; *id.* at 327 n.26 (Greenberg, J., dissenting) ("[T]he *Tampa Electric* standard for Clayton Act Section 3 claims differs very marginally, if at all, from the fact-intensive rule-of-reason analysis that applies to this case under Section 1 of the Sherman Act."); *Dos Santos v. Columbus-Cuneo-Cabrini Med. Ctr*., 684 F.2d 1346, 1352 n.11 (7th Cir. 1982) (noting that *Tampa Electric* applies to Sherman Act cases even though it was decided under § 3 of the Clayton Act))).

Plaintiffs also incorrectly frame their burden in showing exclusion. To support the argument that Section 1 claims require "no" showing of substantial foreclosure at summary judgment, Plaintiffs rely entirely on a summary order. *See Maxon Hyundai Mazda v. Carfax, Inc*., 726 Fed App'x. 66, 69 (2d Cir. 2018) (summary order). But read in context, the Second Circuit in that case merely concluded that a finding that a market was competitive was, alone, an inadequate basis to dismiss a section 1 claim.[9] *Id.* But even if they had articulated the standard properly, Plaintiffs also, for reasons substantially explained *supra* II.B.2.A, fail to demonstrate substantial foreclosure to the required degree, an independently adequate reason for this Court to grant summary judgment here. *See EpiPen II* at 1014 – 15 (consumer class action plaintiffs' calculation of 31% foreclosure insufficient to survive summary judgment as a matter of law where, as here, undisputed evidence shows that "payors could invoke the contracts' termination

[9] Moreover, in its *Mazda* order, the Second Circuit substantially affirmed the district court decision, which did require a showing of substantial foreclosure for an exclusive dealing contract to be unlawful under Section 1 – the precise issue here: "Determining whether a particular exclusive dealing arrangement is unlawful requires a careful analysis of the 'the competitive characteristics of the relevant market. . . . [T]he Supreme Court has long held that 'the competition foreclosed' by such an arrangement 'must be found to constitute a substantial share of the relevant market' in order to violate the antitrust laws." *Maxon Hyundai Mazda v. Carfax, Inc.*, 2016 WL 7231914 at *10, *14 (S.D.N.Y. 2016) (Nathan, J.) (gathering numerous cases).

provisions, and they actually renegotiated their rebate percentages often to secure better pricing from drug manufacturers").

Indeed, Plaintiffs make this very point at other point in their summary judgment briefing. Plaintiffs write that, "Generally speaking, cases . . . have held an agreement must foreclose at least 30 percent to 40 percent of the market to support a § 1 violation," and Plaintiffs also note that the standard used to assess exclusive dealing contracts under Section 1 is more onerous, not less onerous, than that of Section 2. (P. Memo. at 41–43 (quoting *American Express Travel* Related *Servs. Co*. v. *Visa USA*, 2005 WL 1515399 at *3 (S.D.N.Y. June 23, 2005) (Jones, J.); *Dial Corp*., 165 F. Supp. 3d at 36)).

Here, however, as discussed above, the Court reached the conclusion that the challenged contracts were, on net, pro-competitive and not a restraint of trade. As the Supreme Court has long recognized in exclusive dealing cases, in "practical application, even though a contract is found to be an exclusive-dealing arrangement, it does not violate the section unless the court believes it probable that performance of the contract will foreclose competition in a substantial share of the line of commerce affected." *Tampa Elec.*, 365 U.S. at 327. Moreover, Plaintiffs do not have any argument that over 30% of the relevant market has been foreclosed, triggering a broader competition injury.

f. Scienter Standard

Again, for reasons stated substantially above, the Court holds there is no reasonable basis for inferring scienter here, where four different federal judges have previously looked at the challenged transactions and upheld them.

First, whether under Section 1 or Section 2, Mylan's PBM contracts were too short in duration and too easily terminable to amount to a "restraint" on trade. If that is true, then they

cannot have been chargeable with knowledge or recklessness. The MDL court consulted precedent from nearly every circuit and determined that, as a matter of law, Mylan's PBM contracts were too short and too easily terminable to amount to "anticompetitive conduct" as a matter of law. *EpiPen* II at 1009 (gathering cases on duration and terminability).

Second, the ease of terminability and short duration of these contracts were not mere academic concerns; rather, these contracts were genuinely short in duration and the parties to them genuinely did revoke them to gain bargaining leverage with Mylan. The MDL court held that, on a record that is, in this respect, indistinguishable from the one before this Court today, the terminability and durational length limits were not mere window-dressing; they were actually invoked, with frequency, by PBMs and other parties, with clear impacts diminishing price such that "the summary judgment facts establish that payors frequently renegotiated rebate contracts with manufacturers, invoked their early termination provisions, and made changes to formulary coverage and rebate percentages." *Id.* at 1011. Plaintiffs adduce no additional facts, evidence, or legal development that undermine this conclusion. Indeed, if anything, Dr. Ingberman's report is weaker on this point than that of the expert cited by the MDL plaintiffs.

This alone is sufficient to permit a similar application of scienter as in the preceding two sections: Even if Plaintiffs had adduced more evidence to substantiate their antitrust allegations, they still have no evidence permitting a reasonable inference of scienter. As for circumstantial evidence, the short duration and no-fault terminability of the challenged contracts, and the fact that this precise scheme was employed throughout the industry – all facts beyond dispute on the instant record – together make it clear that no reasonable juror could find that Defendants' conduct rose to the level of the "extreme" recklessness that permits an inference of scienter.

III. MDRP Misclassification Claims

Plaintiffs also raise a set of claims related to how Mylan allegedly classified the EpiPen for the purposes of rebates (the same rebates paid to PBMs). This is not an antitrust claim; rather, the crux of Plaintiffs' argument is that the Mylan, with scienter, classified EpiPen as subject to a much lower rebate rate than provided by the Medicaid Drug Rebate Program (MDRP) statute and misrepresented this material fact in statements to shareholders.

For the most part, Plaintiffs' MDRP claims, like the EpiPen competition claims, would require proof of an underlying statutory violation. But, unlike the competition claims, here there are two instances that the Court addresses below where Plaintiffs at least argue that is not the case.

A. Background

1. The MDRP and Regulatory Context

The previous Section dealt with antitrust regulations of Mylan's rebate practices for EpiPen in its PBM contracts. This Section also addresses Mylan's rebating of the EpiPen, but it concerns whether Defendants filed legal documentation with relevant federal agencies and made other statements, including to investors, claiming that its EpiPen product was rebated at a lower rate – and so was more profitable – than was legally proper under the law.

The MDRP is a program authorized by Congress, the purpose of which was "to offset Medicaid costs incurred by the federal government and the states for outpatient drugs provided to Medicaid recipients." *Council on Radionuclides & Radiopharmaceuticals, Inc.*, 2019 WL 5960142, at *2 (D.D.C. Nov. 13, 2019). To achieve this cost-cutting goal and shift expenses back onto manufacturers of lucrative, brand-name drugs, the statute uses rebate rates. Whether a drug is at all eligible for coverage under Medicaid is partially determined at the moment its manufacturer seeks pre-approval from the Food and Drug Administration ("FDA") to introduce

it into the market at all, which is granted or denied by a sub-agency charged with administering the MDRP outside the veteran health context, the Centers for Medicare and Medicaid Services ("CMS"). In order for a drug to be covered by any Medicaid plan anywhere in the country, the statutory architecture first requires that "for covered drugs, a manufacturer must enter a standardized agreement with" the Department of Health and Human Services ("HHS") in the application for the new drug, and "in the agreement, the manufacturer" must promise to "undertake[] to provide [promised] rebates to States" after sale, with these rebate payments going to each state's own state-level agency administering the federal Medicaid program. *See Astra USA v. Santa Clara Cnty.*, 563 U.S. 110, 114–15 (2011) (explaining the background and history of the MDRP). The lower the rebate rate, the less that a manufacturer must pay back to the state governments, and the greater their profits per sale. The higher the rebate, the lower the profits for each drug.

The rub in this case is since the MDRP does not take the simplest path to this goal by setting rebate rates based on whether a drug is patented as a brand-name drug or not. The MDRP did not create a separate agency or process for approving the rate at which an otherwise FDA-approved drug would be rebated; instead, it piggybacks on the existing FDA approval process – meaning that much turns on a manufacturer's opening application for a drug. The percentage of a given drug's price that will be rebated by the manufacturer, under the MDRP, turns partially on which statutory category the drug a manufacturer obtained approval for the drug falling into – (1) "S-drugs," or single source drugs; (2) "I-drugs," or innovator multiple source drugs; and (3) "N-drugs," or non-innovator multiple source drugs. *See* 42 U.S.C. § 1396r-8(k)(7)(A)–(iv). Under the right circumstances, manufacturers of a drug have an incentive to seek approval for their

drugs as "N-drugs," because N-drugs are subject to a lower rebate rate than S- or I-drugs. *See id.* §§ 1396r-8(c)(1)(A)–(B), 1396r-8(c)(3)(B).

Much turns on how a manufacturer fills out its application to CMS seeking to bring a drug to market.[10] The MDRP statute in effect during the relevant time[11] did not purport to define all the relevant words; rather, it defined "single source drug" as "a covered outpatient drug which is produced or distributed under an original new drug application approved by the Food and Drug Administration." *Id.* § 1396r-8(k)(7)(A)(iv). It defines a "multiple source drug" – notably, not a category of drug mentioned for rebating purposes above – as "a covered outpatient drug . . . for which there [is] at least 1 other drug product which—(I) is . . . therapeutically equivalent . . . (II) . . . is pharmaceutically equivalent and bioequivalent . . . and (III) is sold or marketed in the United States during the period." *Id.* § 1396r-8(k)(7)(A)(i). It defines an "innovator multiple source drug" as "a multiple source drug that was originally marketed under an original new drug application approved by the Food and Drug Administration." *Id.* § 1396r-8(k)(7)(A)(iii). Last, it defines "noninnovator multiple source" drug as "a multiple source drug that is not an innovator multiple source drug." *Id.* § 1396r-8(k)(7)(A)(iii).

The only way to have regulatory certainty distinguishing these categories would be a tight definition of "original NDA," but prior to 2007, no statute or rule with force of law defined

[10] The label new drug application (NDA) applies to all new drugs seeking FDA approval. NDAs take two forms. Full NDAs are those approved pursuant to section 505(b)(1) of the FDCA are defined by being submitted with original empirical work, studies, and data that proves the drug's safety and efficacy. (D. SOF ¶ 341.) Second, an abbreviated NDA (ANDA) is submitted without novel studies or data regarding a drug, instead relying on publicly available data or data that the FDA accepted as part of a previous drug application for an "innovator" drug that this one is, in some way, equivalent to. (D. SOF ¶ 342.) The ANDA application goes through a different statutory approval process. *See* 21 U.S.C. § 355(j)(4).

[11] This incarnation of the statute is no longer operative as it has been abrogated. *See STI Pharma*, 2020 WL 1332004, at *3 (citing Medicaid Services Investment & Accountability Act of 2019, Pub. L. No. 116-16, 133 Stat. 852 § 6(c)).

"original NDA." *See STI Pharma, LLC v. Azar*, 2020 WL 1332004, at *4 (D.D.C. March 23, 2020). The 2016 Rule, the last one interpreting the MDRP statute before it was abrogated, saw CMS define "original NDA" as "*typically* to mean an NDA (including an NDA filed under section 505(b)(1) or (2) of the FFDCA), other than an ANDA, which is approved by the FDA . . . ." *STI Pharma*, 2020 WL 1332004 at *5 (citing & quoting *Medicaid Program; Covered Outpatient Drugs*, 77 Fed. Reg. 5,318, 5,190, 5,191 (Feb. 1, 2016). An ANDA, or abbreviated new drug application, is one type of less onerous drug application which, unlike an original NDA, does not require the manufacturer to provide CMS with original empirical research and relies on CMS's approval of prior, similar drugs and studies and equivalent drugs available to the public. In the same act of rulemaking, CMS also opted only to define "single source drug" and "innovator multiple source drug" based on what past practice had shown was "typical[]" of these categories rather than by rule. *Id.* CMS also stated that "[t]here may be very limited circumstances where, for the purposes of the [MDRP], certain drugs might be more appropriately treated as if they were approved under an ANDA and classified as a noninnovator multiple source drug." 77 Fed. Reg. at 5,191.

CMS noted one important example of such an exception: "certain drugs approved under a *paper NDA* prior to the enactment of the Hatch-Waxman Amendments of 1984 or under certain types of *literature-based* 505(b)(2) NDA approvals after the Hatch-Waxman Amendments . . . might be more appropriately treated as if they were approved under an ANDA and classified as a noninnovator multiple source drug, depending on the unique facts and circumstances of the particular situation." *Id.* Accordingly, CMS relied on two additional undefined terms to demarcate the exception: drugs approved under a "paper NDA" and those approved under "certain literature-based NDAs." The term "paper NDA" is a holdover from the rebate statute,

which was not the MDRP, that existed prior to 1984. *See STI Pharma*, 2020 WL 1332004 at *9. It referred to some of the drugs the current MDRP names approved under an ANDA; a drug that was, under the definitions applicable prior to 1984, a "duplicate" drug was said to have been approved under a "paper NDA," which, in turn, grandfathered that drug into the lowest rebate level, like a drug approved pursuant to an ANDA today. *See id.* A "literature-based NDA" is a similar creature, referring to drugs approved after 1984 but before the modern MDRP statute which relied on citations to other NDAs and publicly available literature to explain the drug's purpose and safety to the regulator. *See id.*

2. Challenged Statements

Plaintiffs challenge certain statements and communications by Mylan considered together. Mylan at various points made claims to the effect of, "If ANDA, then 13%." (P. Reply at 3 – 5.) This is said to be misleading because Mylan failed to also disclose that the EpiPen, according to Plaintiffs but contested by Defendants, was also rebated at 13% but was not approved pursuant to an ANDA. (*Id.*)

Plaintiffs raise two types of claims, based on slightly different statements by Mylan. First, Plaintiffs assert claims requiring Plaintiffs to establish that the EpiPen was misclassified and that Mylan knew it for scienter purposes – the more straightforward claims that occupy most of the complaint and Plaintiffs' papers. *See* MTD Op. III at 3 (holding that for most of the MDRP claims, they would fail absent showing "that EpiPen was, in fact, misclassified" and "that Mylan *knew* EpiPen was misclassified"); *see also* MTD Op. I at 24–25; MTD Op. II at 8–9. But Plaintiffs also assert two types of claims that they argue do not require proof of an underlying MDRP violation to establish scienter, dealt with separately under *infra* III.D (Plaintiffs' claims regarding a contrary government position and Mylan's receipt of a subpoena).

B. Scienter

1. "Direct" Evidence of Scienter

Much of Plaintiffs' argument turns on construing the MDRP. But even if Plaintiffs are correct in their reading of the statutory text, liability could only exist if they established the clarity of textual meaning sufficiently to also impute knowledge (scienter) to Defendants.[12] The record supports no such inference; rather, it is replete with evidence tending to significant confusion or disagreement among and within the regulatory agencies. There simply was not a single, clear interpretation of the MDRP statute rendering all the rest unreasonable. Even if Defendants' view of the MDRP was unreasonable, that would not support a reasonable inference of scienter – requiring evidence of "extreme" recklessness, not mere negligence or unreasonableness. *See supra* I.B; II.B.1.a.

The Court concludes that this degree of regulatory uncertainty and confusion, overlayed with the existing factual record, is insufficient to permit a reasonable juror to infer that Mylan knowingly made misleading statements about its classification of the EpiPen.

Though the parties dispute its significance, they both at least agree that Mylan had the following communication with CMS in 1997[13] (the "Powell Letter"):

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[12] Because the Court does not issue a holding on the correct construction of the MDRP, it accepts that Plaintiffs' expert J. Kevin Goroscope, who would testify to the common understanding of the text he gained as a pharmacist in California, as admissible but irrelevant to proving knowledge by Defendants for scienter purposes; that motion is denied as mute. (ECF No. 367.) The Court also denies as moot on this basis Plaintiffs' motion to exclude the testimony of John Shakow, on which the Court need not rely to resolve these motions, and so it is moot. (ECF No. 372.) For substantially the same reason, the Court denies as moot Plaintiff's motion to exclude the testimony of Larri A. Short as unnecessary to reach for disposition of this case. (ECF No. 378.)

[13] Mylan acquired the patent to the EpiPen from Survival, Inc., its predecessor owner, which secured EpiPen's approval under a 1985 (A)NDA. The legal conclusions, if any, compelled by this application are mainly what Plaintiffs rely on to establish scienter.

> Regarding your newly purchased products, EPIPEN and EPIPEN-EZ, product numbers 0301-01, 0302-01, 0303-01 and 0304-01 under labeler number 00268, I have been in contact with Mr. Herb Gerstenzang, FDA in order to determine the Drug Category for you to use when reporting them to us. Because these products are included in a package with a new delivery system, they are listed by the FDA under an NDA (New Drug Application.) The products themselves, however, are listed under an ANDA (Abbreviated New Drug Application) because they are very old products and made by many generic drug companies.
>
> After having a discussion with Herb, we determined that, even though the current NDCs of these products (00268-0301 through 0304) are listed under an NDA, *it is entirely fitting and proper for you to report them to the Drug Rebate Program with a Drug Category of "N" (Non-innovator, Multiple Source) and be subject to the lowest rebate amount of 11 % of quarterly AMP.*

(ECF No. 296 ("D. SOF") ¶ 432 (emphasis added)). Regardless of its legal status, the Court concludes that, at least as of 1997 and until some later date, it was reasonable for both Survivor and its successor at interest, Mylan, to interpret this letter as agency approval for their rebating of the EpiPen at 13%.[14]

To survive summary judgment, Plaintiffs must show that either reliance on this letter was patently unreasonable or that the agency repudiated it. To meet that burden, Plaintiffs direct the Court to four troves of documents. None of this evidence, however, establishes that CMS had clearly informed Mylan that its rebate classification for EpiPen was no longer the law and; this evidence fails to establish that it had become extremely reckless for Defendants to rely on the Powell Letter.

First, Plaintiffs point to the Kirschenbaum Memorandum. (P. Memo. at 8.) But this Memorandum was marked as a "draft," and it represents expressly provisional views ("I look

[14] Plaintiffs raise arguments that suggest a different interpretation of this letter, but none are persuasive and each relies on selective excerpts of the letter via brackets and ellipses in a manner that fails to convey the import of the letter.

forward to your comments . . . ." (ECF No. 335 ("P. SOF") ¶ 1248.) Moreover, the Kirschenbaum Memorandum does not purport to show any kind of unlawful conflict or suggest that Mylan had been previously in error in its classification practices. (*Id.*)

Second, Plaintiffs point to the aforementioned 1997 Powell Letter. (PMSJ1 at 9.) Plaintiffs read this letter to state that EpiPen was approved as a non-innovator drug subject to the lowest rebate. (*Id.*) But for reasons discussed above, while Plaintiffs are correct that this sentence appears in it, this Letter also informed Defendants that they had classified – and most importantly were actually billing – the EpiPen at the entirely proper rate. (*Id.*)

Third, Plaintiffs point to internal communications – such as the Thievon Email (*see* P. Memo. at 9) and Mauro Email (*see* P. Memo. 10) – suggesting that important stakeholders knew that Mylan paid the 13% rebate. This evidence does not establish knowledge as the Court has framed the class's burden. In any event, nothing permits a reasonable of inference of scienter as to non- or misdisclosure on this basis. It is not true that the Defendants had "access to" clearly stated and uncontradicted evidence before them that cast doubt on the honesty of technical statements regarding rebate rates. (P. Memo. at 10, (citing *Novak*, 216 F.3d at 311).)

Fourth, Plaintiffs point to the 2011 and 2013 Saddler Emails. Plaintiffs read the 2011 Saddler Email to state that EpiPen had been misclassified. (P. Memo. at 11; P. SOF ¶¶ 1319 – 20.) This is contradicted by the email itself. This document merely amounts of a request by CMS for Mylan to "ensure" that its currently submitted drug category is accurate. Plaintiffs fail to show that the Saddler Letter should have somehow put Mylan on notice that CMS thought that EpiPen was erroneously classified, let alone that this was in violation of law with sufficient scienter. (*See* P. Memo. at 11.)

The 2013 Saddler Email, by contrast, is specific to EpiPen. (P. SOF ¶ 1323.) But Plaintiffs still place far more weight on it than it can bear. Plaintiffs read this 2013 email to represent CMS conclusively taking a regulatory position "contrary" to Mylan's and CMS's previous position regarding EpiPen classification. (*See* PMSJ1 at 12.) But reading the email in context shows this reading to be contorted and incorrect. The 2013 Saddler Email asks Mylan to "verify" its current classification – much more equivocal language than Plaintiffs' reading would permit. Moreover, Mylan responded – and fiercely contested the notion that EpiPen was misclassified by pointing to prior communications between Mylan and CMS. (PSOF ¶ 1323.) CMS itself seems to admit to the ambiguity that Mylan faced with regard to regulatory compliance after the two Saddler emails: "As explained by CMS . . . , after Mylan responded that they reached out to CMS in 1997 and forwarded a response from Vince Powell stating that noninnovator was appropriate, CMS decided to defer further communication until after the publication of [a pending] final rule" that CMS felt "strengthened [its] position" as to EpiPen's proper "drug category." (PSOF ¶ 1330 (internal quotation marks omitted).) CMS thus did not directly dispute Mylan's communications regarding the Powell letter.

That CMS was not willing to take a position on whether Mylan had misclassified the EpiPen even at this late date is not surprising based on the undisputed record in this case. Prior to 2016, CMS's internal documents show that it did not believe it had a sufficiently clear statutory basis to exclude literature NDAs like that which sought approval of the EpiPen because the text "left room for interpretation." (*See* D. SOF ¶ 430.) Indeed, this position had another kind of benefit for CMS: uncontested evidence shows that it harmonized its rebate classification of the EpiPen with that one that the Veteran's Affairs Department had adopted in the context of its coextensive statutory authority regarding veteran and activity duty health plan coverage. (D.

SOF ¶¶ 442 – 49.) After an audit of Mylan's classification practices wrapped up in 2008, a VA agent stated that "[i]n light of the FDA documents and the 9/29/08 email from FDA Regulatory Counsel that [Mylan] submitted, we agree that EpiPen has a 'paper NDA' (not an 'original NDA') and, therefore, is not a covered drug under 38 U.S.C. 8126" (*see* DSOF ¶ 448), a statutory provision which incorporates all of the MDRP provisions that Plaintiffs rely on by reference. *See* 38 U.S.C. § 8126(h)(2).

Mylan may or may not have been reasonable in relying only on the say-so of CMS, but that is not what the record shows Mylan did. Rather, uncontested evidence shows that Mylan sought opinions of outside counsel which, consulting the significant documents in the record of this litigation, concluded that it was "not necessary" to alter the classification of the EpiPen for MDRP rebate purposes because the "relevant definitions construed in 1997 letter [the Powell Letter] have not changed." (DSOF ¶ 457.)

There is no evidence in the record to sustain a reasonable inference that Mylan knew that EpiPen was erroneously classified and misled its shareholders despite this. At best, the Saddler emails establish that Mylan may have been wrong, which is insufficient to carry Plaintiffs' burden.

Plaintiffs also refer to a 2014 conference call between Mylan and CMS, about which CMS created the following summary:

> [I]t was our belief that drugs approved under an NDA should be reported as innovator. [Mylan] explained that they had the letter from Vince Powell from 1997, which "allowed" them to report as N. Mylan argued that the ingredient epinephrine is an old drug that shouldn't be viewed as a brand name drug. We explained that there was more recent guidance than the "Vince Powell" letter issued, which indicated that NDA approved products should be reported as S or I. [Mylan] then discussed the fact that the NDA approval was not an "original" NDA and used the 1995 proposed rule language as evidence. We told them that the 1995 proposed rule was not

> finalized and should not be relied upon for guidance. [Mylan] also indicated that they had received communication from CMS inquiring about the drug category reporting and in response, they supplied the [CMS Decision] Letter. We told them that manufacturers had a responsibility to report correctly, that the DDR system was "open" for reporting revisions, and that a drug category change could be made by manufacturers that would be retroactive only to 3rd quarter 2014. *They asked if we were requesting that they change their drug category and we said that we were not making that request, however we were communicating to them the field was open and that by making the change while it was open, it would take effect as of 3rd quarter 2014*. We asked them to let us know of their decision by 11/12/14.

(D. SOF ¶ 432 (emphasis added).) Reading the first several sentences (which Plaintiffs quote) in the context of the last two sentences (which Plaintiffs do not) undercuts any reasonable inference that this meeting should have placed Defendants on notice that statements regarding the EpiPen were extremely or egregiously reckless. In fact, Defendants made sure to ask CMS directly if it felt that Mylan needed to change the drug rebate category for EpiPen – and CMS said no.

Plaintiffs place emphasis on an email chain featuring Lara Ramsberg, an employee of Mylan. That email chain ("Rambsberg Email") states:

> Lara Ramsburg forwarded the response to Defendant Bresch and stated, that "consistent with some digging . . . with [PriceWaterhouseCoopers]" the EpiPen was granted generic status "basically as a result of a conversation two guys [] had." She then stated expressly that "all involved believe that if [Sanofi had requested similar status for Auvi-Q] they would have been denied given. . . that ours was a loose interpretation to begin with." Lara Ramsburg stated further, "I've talked further with Rob [O'Neill] and the concern is that if we point out to CMS [the EpiPen's classification] and try to push Auvi-Q to match us, that will result in a fresh look at us that would be harmful, because the benefits of our having this designation are still significant."

(P. SOF ¶ 1429.) But Mylan's concern here – a full year after the 2013 communications – is only that CMS might in the future change its stance, suggesting a widespread and reasonable internal belief on the part of Mylan that it was in compliance with the latest guidance. Plaintiffs

are correct that there is some criticism of the Powell Letter contained here, but it is hardly of the sort that suggests Mylan believed the statements of regulators to no longer apply. In context, those statements appear where Ramsberg suggests that the relative weakness of the Powell Letter could result in its overturning upon a "fresh look," which "could be harmful." In context, therefore, this is only suggestive of Mylan's honestly held belief that it could still rely on the Powell Letter.

Plaintiffs also point to a set of internal documents consisting mainly of emails. Plaintiffs' best piece of evidence on this point is the June 2013 letter from Raymond Urbanski, Mylan's Chief Marketing Officer, and addressed to an employee of one of Mylan's banks. (P. SOF ¶¶ 1410, 1411.) In relevant part, that letter states, "the EpiPen has a design that is fundamentally different from all other epinephrine auto-injectors . . . . [The] FDA has determined that none of the currently approved epinephrine auto-injectors is therapeutically equivalent to any other." (P. SOF ¶¶ 1411, 1412.)

But this does not deal with whether Mylan was egregiously reckless in not interpreting the MDRP in the manner that the Plaintiffs suggest; at most, it supports the meager inference that there were countervailing interpretations during the relevant time, but it does not establish such interpretations as authoritative. Plaintiffs' argument relies on a series of legal and factual inferences, and this evidence does not speak to whether anyone at Mylan knew that if EpiPen lacked therapeutic equivalents as of 2014, that meant it was wrongly classified and therefore rebated at the wrong rate, all despite CMS's statements over the decades that Mylan was rebating the EpiPen correctly. Moreover, this evidence shows that even closely associated financial partners of Mylan were confused or in error (according to Plaintiffs) regarding what Mylan's rebate requirements were. Finally, this evidence, even in the portion excerpted in Plaintiffs'

statement of facts, relies on the syllogism that the EpiPen lacks any therapeutically equivalent because there are *no* therapeutic equivalents for *any* epinephrine autoinjector on the market. If CMS adopted this view as determinative for rebate rates, then it would contradict nearly every non-Mylan classification of an EAI that CMS has ever made or currently makes.[15]

Plaintiffs direct the Court to a West Virginia state court lawsuit in which some of Mylan's papers suggested that the EpiPen was not therapeutically equivalent, but the filings postdate Defendant's allegedly misleading statements challenged here, and so this is irrelevant. (PSOF ¶¶ 1414, 1412.) Plaintiffs then gesture to a 2013 letter sent by Andrea Miller and Urbanski, reiterating that the FDA had classified the EpiPen as lacking therapeutic equivalents. For reasons dealt with regarding the other 2013 Saddler Email, this does not support the inferences that Plaintiffs need to sustain their case.

Plaintiffs also cite a 2015 letter from a Mylan attorney to Florida's local Medicaid administrators arguing that Florida should classify the EpiPen and Sanofi's Auvi-Q product as not therapeutically equivalent. But it is clear from context that this lawyer was discussing what was permissible for local Medicaid authorities to market to local doctors based on Florida law, under which pharmaceuticals are not therapeutic equivalents if "it has not been determined that the selected product would not pose a threat to the health and safety of the patients receiving the

[15] Plaintiffs' references to the 2009 Office of the Inspector General Report (OIG Report) is no more persuasive. (TAC ¶ 77; Contentions, at 20.) The OIG Report does not concern EpiPen. It was never acted upon. And Plaintiffs do not explain what alternative inferences they would have the Court draw from it, in light of the wealth of EpiPen-specific evidence that the Court would much more readily draw inferences from. Indeed, Plaintiffs have not established that EpiPen was one of the anonymous nine drugs that the OIG Report reportedly claimed were misclassified. In any event, the specific approvals from CMS, detailed above, are sufficient to remove any genuine dispute about the weight of the OIG Report.

prescription medication." (P. SOF ¶ 1417 (citing and quoting § 465.025, Fla. Stat., but not citing and quoting any federal statutes or other authorities).)

It may be true that Mylan, for the purposes of internal and external marketing, wanted EpiPen to seem unique and branded. That is not the framework required by the MDRP statute, however, and so these patent applications, and related factual claims, are irrelevant. Given the environment in which Defendants and CMS itself operated during the relevant time, the record here is "antithetical to the notion that defendants engaged in conscious misconduct or reckless behavior." *Funke*, 237 F. Supp. 2d at 468–69 (where the alleged violated accounting rule was ambiguous ex ante and no SEC actions clarified, summary judgment appropriate in case about accounting rules). Any reasonable inference of knowledge or extreme recklessness is precluded by that undisputed evidence that (1) CMS itself could have been mistaken over the meaning of the statute, (2) Defendants sought and obtained repeated exculpatory permission slips from CMS, and (3) the actual nature of EpiPen's first drug application fits neatly into neither the NDA nor ANDA category but, rather, has core attributes of both.[16] *See In re Carter-Wallace, Inc., Sec. Litig.*, 220 F.3d 36, 40, 41–42 (2d Cir. 2000) (applying the recklessness framework to conflicting

[16] Nor does anything stated by the court in *STI Pharma* contradict this conclusion, despite Plaintiffs' suggestion to the contrary. *STI Pharma* held that a "paper NDA" qualifies as an N-drug, and so is an ANDA and should be rebated at the lowest rate. 2020 WL 1332004, at *13. There is some record evidence suggesting that at times CMS and Mylan both referred to the EpiPen's application as a "paper" NDA, and the VA assuredly reached this conclusion. But the Court is not prepared today to break new statutory ground. *STI Pharma*, rather, supports the conclusion that an inference of scienter on these facts would be unwarranted. First, the *STI Pharma* court did not have a holding about general "literature-based" NDAs that lacked original research because that broad issue was not before it; but in dicta, it strongly suggested that such applications would produce the lowest rebate rates, absent some form of real agency or congressional action. *See id.* at *13. The fact that the proper interpretation of this precise statutory provision had to be litigated at all – let alone that CMS was denied *Chevron* deference in its construction, and that the constructing court left many questions unanswered – undermines Plaintiffs' interpretation of the MDRP (which does not even have a consensus today).

regulatory information supplied to a defendant drug manufacturer by the FDA itself, and holding that the ambivalence and lack of clarity in the agency's own communications defeated scienter).

2. "Indirect" Evidence of Scienter

The main indirect evidence Plaintiffs rely on are a settlement Mylan entered with the Department of Justice pertinent to EpiPen's classification and evidence that some employees of Mylan asserted the Fifth Amendment privilege against self-incrimination in depositions as part of that investigation.

Two employees' assertion of privilege fails, in light of all the other evidence, to sustain Plaintiffs' burden. Plaintiffs overstate this argument over the course of their filings – and by oral argument, Plaintiffs asserted that case law in this Circuit "compels" a denial of summary judgment for Defendants on this basis alone. (Oral Arg. at 17.) The authorities that Plaintiffs rely on do not support their position. The primary Second Circuit case on which they rely is postured as rejecting a per se rule against all Fifth Amendment invocation statements being inadmissible in civil proceedings; it notes potentially serious but case-specific issues with the constitutionality and reliability of this type of statement, and it certainly does not counsel a district court to place dispositive weight on such evidence at summary judgment. (*See* P. Memo at 50 (citing *Brink's Inc v City of New York*, 717 F.2d 700, 908 (1983) (rejecting per se rule in civil context)). It is more accurate to say that the rule in this Circuit is that "a motion for summary judgment cannot be granted on an adverse inference alone; rather, the inference must be weighed with the other evidence in the matter in determining whether genuine issues of fact exist." *S.E.C. v. Suman*, 684 F.Supp.2d 378, 386–87 (S.D.N.Y. 2010) (citing *LiButti v. United States*, 178 F.3d 114, 124 (2d Cir. 1999); *S.E.C. v. Pittsford Capital Income Partners, LLC*, 2007 WL 2455124, at *14-15 (W.D.N.Y. Aug. 23, 2007); *S.E.C. v. Invest Better 2001*, 2005 WL 2385452, at *2, (S.D.N.Y. 2005)). Because there are a number of reasons an employee might

assert the Fifth Amendment privilege and Plaintiffs fail to rebut the strong evidence of non-culpability offered by Defendants, the Court concludes that their invocation of the privilege, though perhaps admissible, is not sufficiently probative to give rise to a genuine dispute of material fact.

Second, Mylan's settlement agreement is neither admissible nor significantly probative of scienter. Even if this settlement were admissible evidence,[17] it would not be sufficient to alleviate Plaintiffs' proof problems. Since it is from after the class period, it is largely irrelevant in the context of this securities fraud lawsuit: For scienter purposes, it does not matter what Mylan was willing to settle for in 2017; what matters is what Mylan and its agents knew and believed when the challenged statements were made in 2015. (P. SOF ¶ 1427.)

3. *STI Pharma*

The parties direct the Court to *STI Pharma v. Azar*, decided in 2020, for purposes of construing the MDRP statute. Plaintiffs, in fact, cite it as one basis for their own motion for partial summary judgment, arguing that it clearly disproves the reasonableness of Defendants' views of the MDRP. Because the *STI Pharma* court expressly limited its own holding to defining a pre-1983 statutory usage of "paper NDA," not a term at issue in this litigation, this Court cannot properly rely on it as a basis for summary judgment here. 2020 WL 1332004, at *13. To the extent that *STI Pharma* is persuasive for either party, it strongly suggests that Plaintiffs' construction is at least incomplete and Defendants' is closer to the best statutory meaning:

> Even if all NDAs were . . . "original" new drug applications, and even if no ANDA were . . . "original" new drug applications, those premises have no bearing on STI Pharma's commonsense

[17] *See* Fed. R. Evd. 408 ("Evidence of [accepting a settlement] is not admissible . . . either to prove or disprove the validity or amount of a disputed claim . . . .).

> contention that the paper NDA for Sulfatrim was not the "original" new drug application for that drug. To use an analogy, it is true that all dogs are mammals and that no birds are mammals. But those premises tell us nothing about whether insects are mammals.

Id. at *11. This would support Defendants' construction of the MDRP statute, though it is not dispositive of the proper interpretation of the MDRP, albeit probative as to what reasonable minds may have thought the statute to stand for during the relevant time. Additionally, the *STI Pharma* court considered in detail the extensive regulatory uncertainty surrounding the MDRP for its entire existence and, importantly, declined to apply *Chevron* deference to CMS's own interpretation of the statute, further suggesting that it would be unreasonable to expect Mylan to have accurately construed a statute that even the agency had not done. *See id*. at *8-10. Additionally, there is evidence to suggest that at least some people at Mylan and some people at FDA, during the relevant period, did believe that the EpiPen was "therapeutically equivalent" to other drugs on the market – in fact, this equivalence is, somewhat bizarrely, the entire basis of Plaintiffs' EpiPen competition claims and within the permissible scope as laid out in *STI Pharma*.[18]

[18] Mylan's predecessor at interest, Survival, did not submit an NDA as that term is used in *STI Pharma*, which is yet another reason to grant Defendant summary judgment. First, the submitted application was not, as noted above, an "original" NDA in that it submitted no novel scientific studies and/or datasets but, rather, referenced name-brand epinephrine delivery equivalents that the application assessed as currently available in the market. (D. SOF ¶ 385.) Indeed, the initial NDA filed "was based on evidence that was decades old." (D. SOF ¶ 386.) Survival "conducted no new studies and provided no new data to FDA" in seeking EpiPen's approval, an indicator that one is not pursuing the sort of new drug application that would entail a heightened rebate rate. (*Id*.) At least once a CMS attorney wrote in an email to Mylan that EpiPen's initial application was a nonoriginal NDA: "[I]t is very clear . . . that . . . [the] Epi-Pen [NDA] was a 502(b)(2) application." (D. SOF ¶ 387.) Representatives at the VA, when asked to opine on the current status of EpiPen's initial application, concurred with CMS, writing that "we agree that EpiPen has a 'paper NDA' (not an 'original NDA') and, therefore" is subject to only the 13% rebate. (D. SOF ¶¶ 447, 448.) Given this ambiguity, it is not enough to say that Mylan could have reached the right legal conclusion. Instead, it is enough that Mylan did not act knowingly to mislead investors as to the value of EpiPen to the firm, and, instead, did what other industry players and CMS itself "recognized [as] the appropriate way to categorize a drug

C. Separate Claims

Plaintiffs offer two somewhat different arguments that they should be granted summary judgment on these claims. First, Plaintiffs assert that it is clear from the record that, when the Defendant issued its 2014 statements regarding governmental positions on its MDRP classifications, Defendants knew and affirmatively chose not to disclose that the government – here, CMS – had taken what Plaintiffs see as contrary views to Mylan's about how to rebate the EpiPen. (P. Reply at 5 – 7.) Second, Plaintiffs contend that a government investigation establishes the elements of securities fraud beyond genuine dispute.

1. "Contrary Position"

Plaintiffs argue that, even if Mylan were ultimately right in its classification of the EpiPen, its collateral Statements Explaining Regulatory Risk were materially misleading because Mylan knew at that time that CMS had taken a contrary position.

Plaintiffs first direct the Court to a series of Mylan's 10-K annual reports. (P. SOF ¶¶ 1173 – 77.) In each 10-K, Mylan made no specific statements about the EpiPen or its rebate rate, but generally asserted an opinion of the status quo MDRP compliance and warned investors that the industry was highly regulated, involved subjective judgments, and that this could well "SUBJECT US TO INVESTIGATION, PENALTIES, AND SANCTIONS." (P. SOF ¶ 1176.) The 2011 10-K is different than the other four in that it less explicitly uses language making it clear that some governmental regulators may, in fact, already "have commenced" investigations or other regulatory actions into Plaintiffs.

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approved under an NDA that should be rebated under the Other Drug Rate was to report it as N drug." (D. SOF ¶ 349.) There is also uncontroverted evidence that "hundreds of other drugs approved under NDAs were reported as N drugs and subject to the [13% Rebate] Rate between 2014 and 2016. (D. SOF ¶ 348.)

Plaintiffs next refer to some of Mylan's 10-Q quarterly reports. The April 2012, July 2012, and May 2015 quarterly reports are substantially identical in language, regarding whether the government had taken adverse regulatory actions, to the 2012 10-K: These statements all contained language that "should there be ambiguity with regard to how to properly calculate and report payments – and even in the absence of such an ambiguity – a governmental authority may take a position contrary to a position we have taken . . . ." (PSOF ¶ 1179.)

Plaintiffs then identify additional facts that they argue render the above materially misleading. First, Plaintiffs produce a variety of evidence about James Abrams and Terry Pierce, employees of Mylan responsible for managing relations, contacts, and contracts with state-level Medicaid officials. (P. SOF ¶¶ 1350, 1351.) Abrams was Pierce's supervisor, and together, these two individuals were highly regarded within Mylan as the "contract supervisors" for Medicaid rebating. PSOF ¶¶ 1354, 1355. The record shows that Abrams did a variety of standard corporate officer activity in a highly regulated industry: Abrams, for example, wrote Mylan's comments on CMS's proposed changes to its MDRP rules during the APA-required period. PSOF ¶¶ 1361–67.

This evidence, considered together, fails to support Plaintiffs' position. To prevail would require Plaintiffs to establish that CMS actually had taken an opposing view from that of Mylan regarding how the MDRP statute required Mylan to rebate the EpiPen. For reasons addressed above, there is no reasonable basis in the record to conclude this. Therefore, nothing in these statements is misleading. Similarly, even if there were some basis for a reasonable inference that this was misleading, it would fail for want of scienter, for reasons also explained previously: Mylan reasonably believed the government had not taken a contrary position regarding the EpiPen's classification.

2. Government Investigation

Plaintiffs also argue that the same Statements of Regulatory Risk were misleading because they purportedly implied that Mylan was not yet being investigated by a regulator when, in fact, Mylan had received a federal subpoena related to the EpiPen's rebate classification.

This argument also fails. First, all of the reasons that Mylan may well have thought it was – and, indeed, reasonably thought it was – in the right regarding how it classified the EpiPen are also reasons why no one at Mylan would have had reason to think the subpoena material. That is, if, as the Court has held, Mylan acted reasonably in its reliance on CMS statements and other communications in determining how to rebate the EpiPen, then there is no reasonable basis for Mylan to have regarded the subpoena material. *See generally Dingee v. Wayfair, Inc.*, 2016 WL 3017401, at *5 (S.D.N.Y. May 24, 2016) ("In general, the securities laws should be interpreted in a way that will still encourage disclosures that enlighten and inform investors.")

Second, read in context, Defendants' disclosures on this point were not misleading. Plaintiffs fixate on one excerpted sentence: "Any governmental agencies or authorities . . . may commence, an investigation of Mylan relating to" its rebate practices. (P. Reply at 23.) What Mylan said, however, was that "[a]ny governmental agencies or authorities *that have commenced, or may commence*" such an investigation could pose a material problem for its business. (D. SOF ¶ 119 (emphasis added).) This statement plainly warns of the risk that a government regulator may have initiated an investigation into Mylan's rebating. No statement made by Mylan triggered a predicate duty to disclose as its statements were not misleading. Because Mylan's statements, in context, warned of the "exact risk that materialized," these claims fail. *See In re Coty Inc. Sec. Litig.*, 2016 WL 1271065 at *11 (S.D.N.Y. Mar. 29, 2016) (quoting *In re ProShares Tr. Sec. Litig.*, 889 F Supp.2d 644, 653 (S.D.N.Y. 2012), *aff'd*, 728 F.3d 96 (2d Cir. 2013)).

IV. Generic Drugs Antitrust Claims

Separate from the EpiPen, Plaintiffs claim that Mylan made fraudulent statements explaining its market share and its income in the generic drugs market. Plaintiffs challenge two types of statements as materially misleading due to Mylan's failure to disclose its ongoing participation in various antitrust conspiracies to allocate markets or fix prices in generic drug markets. (P. Memo. at 46 – 57.)

A. Challenged Statements

First, Plaintiffs argue that Mylan's Statements Explaining the Market, which described the generic drug market as "very competitive" and "highly sensitive to price" were misleading because Mylan omitted that, in fact, it was engaged in a broad antitrust conspiracy compromising essentially the entire generic drug market domestically. (P. Memo. at 46.) Second, Plaintiffs argue that Mylan made materially misleading statements when it issued statements describing its financial success, including its profits, but omitted that this success was due in part to Mylan's extensive participation in anticompetitive agreements. (P. Memo. at 46 – 47.) Plaintiffs argue that both types of statements are actionable for the same two reasons: Mylan engaged in *per se* illegal market allocation in the generic drug market or *per se* illegal price fixing in the generic drug market. (*Id.*)

B. Procedural Issues

The Court previously held that, to survive at summary judgment, Plaintiffs must demonstrate that Mylan violated the Sherman Act in a manner also satisfying the elements of a securities fraud claim – including loss causation and scienter – for each individual generic drug challenged. *See* MTD Op. III at 8 (dismissing general allegations and claims based on lists of allegedly price-fixed or market allegations as "forfeited") (citing MTD Op. II at 14 – 15).

1. Market Allocation Claim

As for the market allocation claims, Plaintiffs attempt to meet this standard only for six drugs – Doxy DR, Tolterodine ER, Fenofibrate, Capecitabine, Valsartan/HCTZ, and Clonidine. (*See* P. Memo. at 52, 55, 57, 59, 60 – 61, 62, 63 – 64.) With the exception of these six drugs, Plaintiffs have forfeited any other generic drug market allocation argument against Mylan, and such outstanding claims are dismissed with prejudice for reasons substantially explained in this Court's second and third opinions on motions to dismiss in this case. *See* MTD Op. II at 14 – 15; MTD Op. III at 8.

2. Price-Fixing Claim

The same procedural deficiency dooms all of Plaintiffs' arguments about price-fixing. Plaintiffs must make out the Sherman Act component of this claim on a drug-by-drug basis and must demonstrate scienter and loss causation using specific evidence, on a drug-by-drug basis, not general statements about the nature of the drug industry. Plaintiffs have never clearly articulated which drugs fall into the category of the so-called "Price Fixed Drugs" in this case. It is true that Dr. Ingberman's Report does name the so-called Price-Fixed Drugs,[19] but Plaintiffs elsewhere clarify that this is not meant to be legal analysis. (*See* ECF No. 415 at 6 ("Dr. Ingberman's opinion remains an opinion about the economic concept of collusion [not the legal concept].").)

Additionally, whether Dr. Ingberman's Report does or does not "provide[] extensive analytical support for the application of the 'plus factors' he identifies to the markets for each of

[19] The Court accepts without deciding that Dr. Ingberman's Report regarding generic drugs would be admissible evidence. Defendants' motion *in limine* to exclude Dr. Ingberman's generics report is thus denied as moot. (ECF No. 376.) The Court also accepts without deciding that Todd Clark's Report regarding generic drugs is admissible and similarly denies Defendants' motion to exclude his testimony as moot. (ECF No. 360.)

the Generic Drugs" is beside the point. (*Id.* at 14.) The Supreme Court has emphasized the importance of formal compliance with the pleading requirements to establish specific agreements in all Section 1 cases because such cases raise particularly serious risks with respect to vexatious suits. *See Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 557 (2007). Here, Plaintiffs have failed to meet bare minimum threshold requirements for clearly defining their claims.

Plaintiffs rely on the public announcement of government investigations of Mylan's generic drugs as "probative of conspiracy." (P. Memo. at 49 (quoting *Starr v. Sony BMG Music Ent.*, 592 F.3d 314, 325 (2d Cir. 2010).) This approach is unpersuasive. Plaintiffs lump all adverse statements, invocations of the privilege, and co-conspirator statements into one, suggesting a general conspiracy with respect to all parts of the generic drug market. As the Court has explained, however, this is not how the Sherman Act works. Plaintiffs fail to draw out reasonable connections and inferences. A Mylan employee invoking the Fifth Amendment privilege in response to a deposition question about Drug X does not provide a reasonable basis for inferring an illicit conspiracy with respect to Drug Y. Plaintiffs do not attempt to draw these inferences themselves, and the Court cannot do it for them.[20]

C. Section 1 Claims

To survive summary judgment on a parallel conduct claim in a concentrated market like generic drugs, plaintiffs must adduce evidence that "tends to exclude" the possibility of

[20] The first set of testimony that Plaintiffs rely on to argue for an inference of conspiracy consists of Defendant Nesta and Michael Aigner, non-party Mylan employee, both invoking the Fifth Amendment privilege in depositions. The extent to which Plaintiffs have drawn an implication from this fact is as follows: "Nesta . . . and Aigner asserted their Fifth Amendment privileges against self-incrimination in response to questions concerning whether Defendants participated in market allocation and price-fixing conspiracies." (P. Memo. at 50.) Plaintiffs do not articulate what the specific questions where or in what manner they would be probative of the existence of agreements to allocate a specific market or fix the prices for a specific drug. To support their arguments here, Plaintiffs refer to authority that fails to support their position.

independent, non-culpable action. To meet the "tends to exclude" threshold, the Second Circuit requires a plaintiff to adduce evidence showing that it is at least not "equally likely" that conduct resulted from independent action as opposed to coordinated agreement. *United States v. Apple*, 791 F.3d 290, 315 (2d Cir. 2015 (citing *Matsushita*, 475 U.S. at 588). Thus, to survive summary judgment in a parallel conduct case, a plaintiff must produce "direct or circumstantial evidence that reasonably tends to prove that the [defendants] had a conscious commitment to a common scheme designed *to achieve an unlawful objective*" to satisfy the conspiracy element of Section 1. *Apex Oil Co. v. DiMauro,* 822 F.2d 246, 252 (2d Cir. 1987) (emphasis added) (quoting *Monsanto Co. v. Spray-Rite Service Corp.*, 465 U.S. 752, 764 (1984)). "At a minimum," Plaintiffs must adduce evidence of circumstances "such as to warrant a jury finding that the conspirators had a unity of purpose or a common design and understanding, or a meeting of the minds in an unlawful agreement." *Apex Oil*, 822 F.2d at 252 (quoting *Intern. Distribution Ctrs., Inc. v. Walsh Trucking Co.*, 812 F.2d 786, 793 (2d Cir. 1987); *Michelman v. Clark-Schwebel Fiber Glass Corp.*, 534 F.2d 1036, 1046 (2d Cir. 1976), *cert. denied,* 429 U.S. 885 (1976)).

1. Standard for Oligopolistic Markets

The Court assumes familiarity with the background of Section 1 liability. *See supra* II.B.3. Here, the Court focuses on the elements and arguments as applicable to the generic drug market. Again, there are two elements of a Section 1 claim: A plaintiff must prove (1) agreement, (2) a restraint on trade that unreasonably interferes with competition. *Id.*

What differentiates this analysis from the Section 1 analysis above are uncontested market conditions. Plaintiffs have not contested that the relevant markets for specific generic drugs are properly characterized as oligopolistic, substantially changing player incentives and elevating Plaintiffs' burden of proof in a variety of ways. This notion — sometimes called market concentration, tacit collusion, or oligopolistic coordination — "describes the process, not

in itself unlawful, by which firms in a concentrated market might in effect share monopoly power, setting their prices at a profit-maximizing, supracompetitive level by recognizing their shared economic interests and their interdependence with respect to price and output conditions." *Brooke Grp*., 509 U.S. at 227.

Since Section 1 "of the Sherman Act 'does not prohibit all unreasonable restraints of trade . . . but only restraints effected by a contract, combination or conspiracy,' . . . 'the crucial question' is whether the challenged anticompetitive conduct 'stems from independent decision or from an agreement, tacit or express." *Twombly*, 550 U.S. at 554 (cleaned up) (quoting *Copperworld Corp. v. Independence Tube Corp.*, 467 U.S. 752, 775 (1984); *Theatre Ents., Inc. v. Paramount Film Distributing Corp.*, 346 U.S. 537, 540 (1954)). Even knowing "conscious parallelism" represented by a "common reaction of firms in a concentrated market [which] recognize their shared economic interests and their interdependence with respect to price and output decision . . . is not in itself unlawful." *Twombly*, 550 U.S. at 554 (quoting *Brooke Grp.*, 509 U.S. at 227). At a minimum, sufficient proof to establish a Sherman Act conspiracy under Section 1's restraint of trade provision requires evidence which "*must* tend to rule out the possibility that defendants were acting independently" to survive summary judgment." *Id.* (emphasis added) (quoting *Matsushita.*, 475 U.S. at 588).

"[I]n oligopoly cases in particular," courts require plaintiffs to satisfy certain "specialized evidentiary standards," *see Valspar*, 873 F.3d at 193, such as evidence that "tends to exclude" the possibility that defendants acted independently in response to common market stimuli and mutually held incentives. *Matsushita*, 475 U.S. at 588. It is therefore more difficult to adduce proof that could support a reasonable inference of an agreement in an oligopolistic market versus more normal market conditions. "Even though . . . interdependence or 'conscious parallelism'

harms consumers just as a monopoly does, it is beyond the reach of the antitrust laws" because, either it falls short of the statutory meaning of "agreement" for Section 1 purposes, or because there would be no conceivable judicial remedy. *Valspar*, 873 F.3d at 191 (quoting *In re Flat Glass Antitrust Litig.*, 385 F.3d 350, 360 (3d Cir. 2004); *Clamp-All Corp. v. Cast Iron Soil Pipe Inst.*, 851 F.2d 478, 484 (1st Cir. 1988)). "Oligopolies pose a special problem under § 1 because rational independent actions taken by oligopolists can be nearly indistinguishable from horizontal price fixing . . . [as a] result of 'interdependence,' which occurs because 'any rational decision [in an oligopoly] must take into account the anticipated reaction of the other firms." *Id.* at 191 (quoting *Flat Glass*, 385 F.3d at 359). To survive summary judgment on a Section 1 claim in the context of an oligopoly, substantive antitrust law elevates a plaintiff's evidentiary burden. "The extent of which constitutes a reasonable inference in the context of an antitrust case . . . is . . . different from cases in other branches of the law in that 'antitrust law limits the range of permissible inferences from ambiguous evidence in a § 1 case.'" *Baby Food*, 166 F.3d at 124 (quoting *Matsushita*, 475 U.S. at 588). In a case like this one, "evidence of plus factors must tend to exclude the possibility of independent conduct." *Monsanto*, 465 U.S. 764.

The plus factors are necessary, not sufficient, and are still subject to case-specific assessment by the court since "such plus factors may not necessarily lead to an inference of conspiracy." *Apex Oil*, 882 F.2d at 254. In fact, "such factors in a particular case could lead to an equally plausible inference of mere interdependent behavior, *i.e.*, actions taken by market actors who are aware of and anticipate similar actions taken by competitors, but which fall short of a tacit agreement." *Id.* Summary judgment against plaintiffs is warranted if a court finds "it difficult to hold that the parallel acts 'tend to exclude the possibility' of independent action"

because "a court must remember that often a fine line separates unlawful concerted action from legitimate business practices." *Baby Food*, 166 F.3d at 253 – 55 (internal citations omitted).

2. Market Allocation Claim

Antitrust law places limits on the permissible inferences a court may draw from certain types of evidence. Direct evidence is subject to minimal constraints. "Direct evidence in a Section 1 conspiracy must be evidence that is explicit and requires no inferences to establish the proposition or conclusion being asserted." *Baby Food*, 166 F.3d at 118; *accord O.E.M. Glass Network, Inc. v. Mygrant Glass Co., Inc.*, 436 F. Supp. 3d 576, 587 (E.D.N.Y. 2020); *cf. Citigroup*, 709 F.3d at 136 (giving examples of direct evidence). Here, Plaintiffs adduce circumstantial evidence, and they must therefore show the existence of plus factors.

The plus factor analysis is also affected by the oligopoly context. "Because the evidence of conscious parallelism is circumstantial in nature, courts are concerned that they do not punish unilateral, independent conduct of competitors." *Baby Food*, 166 F.3d at 122. Anticipating this problem, courts require plaintiffs to show "plus factors" which act as legally "necessary conditions for [any] conspiracy inference." *Id.* at 123. However, establishing one such plus factor is not dispositive. The plus factors are necessary but not sufficient conditions for surviving summary judgment; a court must be satisfied that such evidence would be sufficient to permit the inference of "an illegal conspiracy between the parties," because, even if some plus factor is present, it may still be the case that "the defendants acted independently of one another, and not in violation of the antitrust laws." *Baby Food*, 166 F.3d at 122 (quoting *Balaklaw v. Lovell*, 822 F. Supp. 892, 892 (N.D.N.Y. 1993)).

The plus-factor requirement applies equally whether the primary mechanism of exclusion is price or market allocation. *In re Interest Rate Swaps Antitrust Litig.*, 261 F. Supp. 3d 430, 463 (S.D.N.Y. 2017) (applying plus factors to output and allocation based Section 1 allegations

because "[p]ost-*Twombly* courts have analyzed [all] § 1 claims based on parallel conduct by horizontal competitors by inquiring whether 'plus factors' . . . are present" (citing *Citigroup*, 709 F.3d at 137; *Gelboim v. Bank of Am. Corp.*, 823 F.3d 759, 779 (2d Cir. 2016)).

Here, nearly all of the plus-factor evidence identified by Plaintiffs only amounts to "evidence that the defendant had a motive to enter into a[n antitrust] conspiracy" which "may indicate simply that the defendant had a motive to enter in an oligopolistic market." *Citigroup*, 709 F.3d at 139. Here, Plaintiffs' arguments about motive and opportunity "simply restate the (legally insufficient) fact that market behavior is interdependent and characterized by conscious parallelism." *Id.* These arguments are insufficient to carry Plaintiffs' burden.

Plaintiffs also argue for a third plus factor based on the notion that Defendants failed to take sufficient advantage of competitive opportunities in marketing generic drugs in the U.S. But Plaintiffs' analysis of this plus factor relies on a mistaken syllogism. The antitrust laws do not impose "a duty on firm to compete vigorously, or, for that matter, at all . . . ." *In re Text Messaging Antitrust Litig.*, 782 F.3d 867, 873, 874 (7th Cir. 2015) (Posner, J.) ("It is one thing to prohibit competitors from agreeing not to compete; it is another to order them to compete. How is a court to decide how vigorously they must compete in order to avoid being found to have tacitly colluded in violation of antitrust law?").

Plaintiffs face a significant proof hurdle: To challenge Mylan for insufficiently competing, they need to show that Defendants acted in bad faith such that they should be denied the traditional protections accorded "business judgment." *See Cayman Expl. Corp. v. United Gas Pipe Line Co.*, 873 F.2d 1357, 1361 (10th Cir. 1989). Stated in the context of Plaintiffs' market allocation claims, when such allegations are "equally consistent with" conduct indicating only "a natural and independent desire to avoid a turf war" and associated costs, they are

insufficient as a matter of law to infer an agreement in an oligopolistic market sector. *See In re Zinc Antitrust Litig.*, 155 F. Supp. 3d 337, 375 (S.D.N.Y. 2016).

Here, this hurdle is insurmountable. Both of Plaintiffs' experts on this issue acknowledged that conceding market share to opponents or choosing not to fill some sales opportunities can be entirely consistent with a firm's unilateral self-interest, provided that firm operates in a sufficiently oligopolistic environment. (D. SOF ¶¶ 610, 620.) Courts have taken this conclusion even further, recognizing that this type of Section 1 allegation creates a "substantial" burden on the Plaintiff and requires them "to produce evidence which 'tends to exclude the possibility that defendants were acting independently.'" *In re Chocolate Confectionary*, 999 F. Supp. 2d 777, 791 (M.D. Pa. 2014), *aff'd*, 801 F.3d 383 (3d Cir. 2015). Plaintiffs have made no such showing.[21]

a. Doxy DR

Plaintiffs' evidence of an agreement to allocate the Doxy DR market rests largely on the Glazer Affidavit. (*See* P. Memo. at 52 – 54.) This evidence is not direct evidence for reasons discussed above. Glazer himself noted that Mylan's representative at the meeting, Malik, was non-committal. Thus, to find a conspiracy on the basis of this evidence, a finder of fact would need to infer that a subsequent communication or action represented Mylan's at least tacit assent to the agreement. The rest of the evidence that Plaintiffs adduce (consisting of emails and calls spanning May to August 2013) shows only information sharing between rivals in an oligopolistic

[21] Plaintiffs' remaining argument is that certain Mylan employees' invocations of the Fifth Amendment privilege suffice to infer a conspiracy. However, drawing an adverse inference based on this, and nothing more, is impermissible; corroboration is required. *Lefkowitz v. Cunningham*, 431 U.S. 801, 808 n. 5 (1977).

market, which courts have consistently held to be insufficient, standing alone, to establish Section 1 liability in that context.

Plaintiffs identify several plus factors. First, Plaintiffs contend that Defendants had "motive" and "opportunity" to allocate markets in the generic drug sector. This sort of claim, if true, would be only weakly probative of the existence of a conspiracy with respect to each claimed drug. (P. Memo. at 52.) Second, Plaintiffs contend that "Mylan and other alleged cartel members acted in ways that would be contrary to their mutual self-interest." (ECF No. 415 at 1.) Notably, Plaintiffs assume that the same plus-factor analysis will get them through on each of these drugs. That assumption is wrong, and the analysis of these generically framed plus factors will not be repeated on a drug-by-drug basis.

Both claims, if true, are insufficient given the oligopolistic context in which Mylan operated. Courts consider these two factors (evidence that the defendant had motive and opportunity to enter a price-fixing conspiracy and evidence that the defendant acted contrary to its self-interest) irrelevant in an oligopoly case. It is true, as Plaintiffs assume, that "normally all three plus factors are weighed together," but it is equally so that "in the case of oligopolies the first two factors are deemphasized because they 'largely restate the phenomenon of interdependence.'" *Valspar*, 166 F.3d at 193 (quoting *Flat Glass*, 385 F.3d at 360). And interdependence, including conscious parallel price and output increases, is not unlawful even if its effects are the same as a monopolized market for consumers absent some evidence of agreement.

Also, Plaintiffs' analysis of motive as a plus factor is defective. It is true that firms have some incentive to cut corners on legal compliance in order to maximize profits, but that is the only thing that Plaintiffs offer as evidence of Mylan's motivations. This cannot generate a

sufficient reasonable inference at summary judgment. "[I]f . . . the defendants had a motive to achieve higher prices, then every company in every industry would have such a motive." *Baby Food*, 166 F.3d at 133; accord *Apex Oil*, 822 F.2d at 254.

Finally, Plaintiffs argue that their evidence shows that Defendants' conduct in the generic drug market was "against self-interests." But to be sufficient to imply a conspiratorial agreement under Section 1, "evidence of action that is against self-interest or motivated by profit must go beyond mere interdependence. Parallel pricefixing [and other conduct] must be so unusual that in the absence of an advance agreement, no reasonable firm would have engaged in it." *Baby Food*, 166 F.3d at 135 (citing *Coleman v. Cannon Oil Co*., 849 F. Supp. 1458, 1467 (M.D. Ala. 1993)). Defendants have explanations for why a reasonable firm would coordinate in the manner they did, and they further show that it is an industrial standard. *See Brooke Grp.*, 509 U.S. at 235.

b. Tolterodine Extended Release

Plaintiffs claim that Mylan conspired with competitor Teva to allocate markets for Toletordine Extended Release ("TER"). (P. Memo. at 56 – 57.) Plaintiffs lack direct evidence of an agreement and instead rely on a series of call logs between individuals at Mylan and Teva and evidence of internal communications at Teva, not Mylan. (*Id*.)

However, the kinds of communications between various Mylan employees and Teva employees that Plaintiffs identify are not the sort of unreasonable inter-firm communications that can generate a reasonable inference of an illicit agreement. Instead, these sorts of communications are immunized from Section 1 liability because "communications between competitors do not permit an inference of an agreement to fix prices unless 'those communications rise to the level of agreement, tacit or otherwise." *Baby Food*, 166 F.3d at 125

(internal citations omitted). Similarly, "[c]onscious parallelism . . . will not be inferred merely because the evidence tends to show that a defendant may have followed a competitor's price increase." *Baby Food*, 166 F.3d at 128 (citing *Theatre Enterprises v. Paramount Films Dist. Corp.*, 346 U.S. 537, 541 (1954)). This claim fails as a matter of law.

c. Fenofibrate

Plaintiffs also claim that Mylan conspired with Teva and Luna to allocate markets for Fenofibrate. (P. Memo. at 58 – 59.) Plaintiffs' evidence about Fenofibrate is insufficient to generate an inference of anything beyond ordinary firm communications in an oligopolistic market. As to the last point, the only evidence Plaintiffs cite is evidence that Mylan competitors Teva and Lupin appeared to know Mylan's planned launch date prior to its public disclosure. (P. Memo. at 59.) But for reasons explained above, this evidence is "ambiguous" and so insufficient to withstand summary judgment because it is consistent with lawful conscious parallelism and competitor market research and prediction. *See Brooke Grp.*, 509 U.S. at 235.

d. Capecitabine

Plaintiffs further claim that Mylan and Teva conspired to allocate the market for the drug Capecitabine. (P. Memo. at 60.) Plaintiffs' evidence is circumstantial. First, they point to the fact that a Teva employee, Reckenthaler, correctly predicted Mylan's rough targeted market share. (*Id.*) This evidence is probative that Reckenthaler was an effective Teva employee in an oligopolistic setting that incentivized attention to the behavior of rivals, for reasons explained above. Other evidence suggests communications between Reckenthaler and Defendant Nesta. (*Id.*)

This is insufficient to create a genuine dispute as to this claim. It is not evident what the content of the conversation was. Nothing in Dr. Ingberman's Generics Report disturbs this

conclusion either, because he cites only Teva-side communications which, without more, cannot give rise to a genuine dispute for trial.

e. Valsartan/HCTZ

Plaintiffs claim that Mylan conspired with Sandoz to allocate the market for Valsartan/HCTZ ("VHCTZ"). (P. Memo. at 62.) Plaintiffs rely on two pieces of evidence with respect to VHCTZ. First, they isolate communications from Kellum, a Sandoz employee, in which he stated that he did not want to "disrupt" this "two-player market." (P. Memo. at 62.) This showing is insufficient at summary judgment. This is a two-player oligopolistic market, and attention by one firm to how its conduct might disrupt supply or output for another competitor is rational and legal. Subsequent communications about a one-off Walgreen's order that Plaintiffs refer to are unavailing because they do not represent any definitive action or any factual collusion that would disrupt the above conclusion.[22] *See Reserve Supply Corp. v. Owens-Corning Fiberglass Corp.*, 971 F.2d 37, 50 n. 9 (7th Cir.) (evidence of one party inviting another to collude insufficient to infer agreement).

Additionally, none of the individuals identified as communicating about this drug had pricing or market allocation authority, which independently warrants summary judgment. *See Baby Food*, 166 F.3d at 125 ("Evidence of sporadic exchanges of shop talk among field sales representatives who lack pricing authority is insufficient to survive summary judgment."); *Reserve Supply Corp. v. Owens-Corning Fiberglass Corp.*, 799 F. Supp. 840, 843 (N.D. Ill. 1990) (summary judgment granted where person communicating with competitor "had no pricing authority"), *aff'd*, 971 F.2d 37 (7th Cir.).

[22] Plaintiffs point to Sandoz's deferred prosecution agreement. (P. Memo. at 62.) However, this agreement is specific to certain drugs, none of which are challenged here. (*See* P. SOF ¶ 2088.)

f. Clonidine

Plaintiffs claim that Mylan conspired with Teva to allocate the market for Clonidine. (P. Memo. at 63.) As Plaintiffs themselves are forced to admit, much of the evidence adduced here is probative that there was competition in this space between Mylan and Teva. (*Id.*) Plaintiffs' spin is that there was extensive allocation competition at one time, but that sometime later Teva emails show a proposal to cede Clonidine customers to Mylan. (*Id.*)

But Teva's emails show that that never happened: As Plaintiffs rightly acknowledge, those customers were not ceded in the context of Clonidine (or any other drug). (P. Memo. at 64.) Plaintiffs also rely on internal Teva emails suggesting, among other things, that Mylan would "go along" with a price hike. (*Id.*) Plaintiffs highlight emails from Levinson, a Teva employee, in which he expresses his opinion that Mylan was planning "to concede" aspects of this market to Omnicare. (*Id.*) For reasons explained above, this is the sort of conscious parallelism that is not implicated by the antitrust laws in the context of oligopolies.

3. Price-Fixing Claim

As explained above, Plaintiffs rely on circumstantial evidence to infer the existence of an agreement to fix prices; therefore, they must adduce evidence that Defendants engaged in an agreement and that is inconsistent with non-culpable explanations such as oligopolistic incentives.

The concession of Defendants' oligopoly framing is debilitating to the price-fixing arguments. The daylight between legally permissible oligopolies and impermissible monopolies is particularly difficult to pin down in the context of price conspiracies. In an oligopolistic market, "[a] firm is unlikely to lower its prices in an effort to win market share because its competitors will quickly learn of that reduction and match it, causing the first mover's profits to decline." *Valspar*, 873 F.3d at 191. And, again unlike a more traditional setting, when an

oligopolist "firm announces a price *increase*," its rival oligopolists, by definition, "will know that if they do not increase their prices to [that] level, the first mover may be forced to reduce its price." *Id.* Without at any point violating the antitrust laws, oligopolist firms "will consider whether it is better off when all are charging the old price or the new one" and, as such, would "choose the new price" only at the precise moment they believe it will maximize their profits. *Id.* (quoting *Brooke Grp.*, 509 U.S. at 227.

Plaintiffs do not contest this was a price oligopoly, and their experts admit it expressly. As noted above, Plaintiffs chose to refer to the drugs as "the Price-Fixing Drugs" without at any point naming them or attempting to make any arguments based on direct evidence or circumstantial evidence, such as agreement- or drug-specific plus factors. Plaintiffs rely on the same plus factors for this generic drug allegation as they do for their market allocation claim; the Court has already rejected the legal sufficiency of those plus factors and the evidence underlying them. In an oligopoly, inferences suggesting liability drawn only from list price data, or other publicly available price data, are unreasonable as a matter of law. As the Supreme Court has recognized, once one is "in an oligopoly setting," that suggests "price competition is most likely to take place through less observable means than list prices" and so "it would be unreasonable to draw conclusions about the existence of tacit coordination or supercompetitive pricing from [such] data . . . ." *Brooke Grp.*, 509 U.S. at 236.

The failure of Plaintiffs to deal with Mylan's explanation of what economic rationality entails in the generic drug market makes it impossible to conclude that "no reasonable firm would have engaged" in Defendants' course of conduct absent being party to a conspiracy. Plaintiffs' claims therefore fail to survive summary judgment. *See supra* IV.B.1.

D. Loss Causation

1. Standard

To satisfy their summary judgment burden, Plaintiffs must establish loss causation for each concealed conspiracy discussed above. *See supra* I.B. "Loss causation 'is the causal link between the alleged misconduct and the economic harm ultimately suffered by the plaintiff.'" *Lentell v. Merrill Lynch & Co.*, 396 F.3d 161, 172 (2d Cir. 2005).

To establish loss causation under the securities laws, "a plaintiff must show that the 'loss [was a] foreseeable' result of the defendant's conduct (*i.e.*, the fraud), '*and* that the loss [was] caused by the materialization of the . . . risk' concealed by the defendant's alleged fraud." *In re Vivendi S.A. Sec. Litig.*, 838 F.3d 223, 261 (2d Cir. 2016) (quoting *Lentell v. Merrill Lynch & Co.*, 396 F.3d 161, 172 (2d Cir. 2005)). The Second Circuit has cautioned that these are not entirely separate inquiries, and has analyzed the implication of this for the overall quantum of evidence plaintiffs must present to prevail. The court has stated that "proof of loss causation requires demonstrating that 'the *subject* of the fraudulent statement or omission was the cause of the actual loss suffered.'" *Vivendi*, 838 F.3d at 261 (quoting *Suez Equity Investors, L.P. v. Toronto-Dominion Bank*, 250 F.3d 87, 95 (2d Cir. 2001)). Thus, a plaintiff succeeds in adducing evidence for loss causation "[i]f 'the relationship between the plaintiff's investment loss and the information misstated and concealed by the defendant . . . is sufficiently direct." *Id*. at 261 (quoting *Lentell*, 396 F.3d at 174). But courts dismiss cases on loss causation if a plaintiff can only show an "attenuated" connection. *Vivendi*, F.3d at 261. Therefore, "if the plaintiff fails to 'demonstrate a causal connection between the content of the alleged misstatements or omissions and the harm actually suffered,' a fraud claim will not lie." *Id.* (quoting *Emergent Cap. Inv. Mgmt., LLC v. Stonepath Grp., Inc*., 343 F.3d 189, 199 (2d Cir. 2003)).

In some factual contexts, "to show loss causation, it is enough [for the plaintiff to show] that the loss caused by the alleged fraud results from the 'relevant truth . . . leaking out.'" *Vivendi*, F.3d at 261 (quoting *Dura Pharm., Inc. v. Broudo*, 544 U.S. 336, 342 (2005)). The Second Circuit has stated that "a plaintiff can establish loss causation either by showing a 'materialization of risk' or by identifying a 'corrective disclosure' that reveals the truth behind the alleged fraud," but it has clarified that its "past holdings do not suggest that 'corrective disclosure' and 'materialization of the risk' create fundamentally different pathways for proving loss causation . . . ." *Vivendi*, F.3d at 261 (quoting *Carpenters Pension Trust Fund of St. Louis v. Barclays PLC*, 750 F.3d 227, 223 (2d Cir. 2014); *Omnicom* II at 513). Materialization of risk should be "understood . . . as reflective of the principle that 'to establish loss causation, [plaintiffs must show that a] . . . misstatement or omission concealed *something* from the market that, *when disclosed*, negatively affected the value of the security." *Vivendi*, F.3d at 261 – 62 (quoting *Lentell*, 396 F.3d at 172) (emphasis in original). *Vivendi* held the evidence sufficient such to permit a reasonable juror to infer loss causation such that "the *subject* of Vivendi's alleged misstatements . . . was . . . 'the cause of the actual loss suffered'" by the plaintiffs. This was based primarily on (1) expert testimony that the defendant's own behavior (a massive asset dump just nine days after affirming its liquidity to investors) revealed its then-secret internal liquidity crisis; (2) the defendant's own fact witnesses essentially agreeing with this in deposition and open court; and (3) broad acceptance of the economic theory animating this analysis (liquidity shocks) within the relevant academic field. *Id.* at 263 (quoting *Suez Equity*, 250 F.3d at 95). The key was that "misrepresentation is 'the proximate cause of an investment loss [only] if the risk that caused the loss was within the zone of risk *concealed* by the misrepresentations . . . ." *Omnicom* II at 513. Where the information was publicly known at the time of the

defendant's alleged misstatements, the fraud claim fails, because nothing in the record would support the inference that the defendant altered the total available mix of available information. *Id.* at 514. Finally, to qualify as a corrective disclosure, Plaintiffs must show that such a disclosure contains "new fraud-related information." *In re Xerox Corp. Sec. Litig.*, 935 F. Supp. 2d 448, 495 (D. Conn. 2013), *aff'd sub nom. Dalberth v. Xerox Corp.*, 766 F.3d 172 (2d Cir. 2014).

2. Analysis

To survive summary judgment on loss causation, Plaintiffs "must 'establish two causal connections: a connection between the alleged false or misleading statements and one or more events disclosing the truth concealed by that fraud, and a connection between these events and actual share price declines.'" *Moody's*, 2013 WL 4516788 at *10. To establish the connection between the misleading statements and an event disclosing the truth concealed sufficiently for summary judgment purposes, a plaintiff must show "(1) that these events were foreseeable consequences of the alleged fraud; and (2) that these events revealed new information previously concealed by defendants' alleged fraud." *Vivendi*, 634 F. Supp. 2d at 365 (citing and quoting *Lentell v. Merrill Lynch & Co., Inc.*, 396 F. 3d 161, 177 (2d Cir. 2005)). And to establish the connections between disclosure and share price sufficiently for summary judgment purposes, a plaintiff must "(1) show a correlation between news of the event and the declines [in share price]; and (2) disaggregate the declines or some rough percentage of the declines from possess resulting from other, non-fraud related events." *Id.* (citing *Lentell*, 396 F. 3d at 177).

In this case, Plaintiffs' failure to "disaggregate" the losses stemming from a variety of different drugs is a failure to satisfy their summary judgment burden on loss causation. Disaggregation is a threshold evidentiary showing that a plaintiff must meet to withstand summary judgment. *See id.* at 365. Summary judgment for Defendants is warranted because

there is no showing of disaggregation: Plaintiffs treat all these drugs "as one" and seek to draw inferences of general damage to shareholder value based on, essentially, anything negative that was associated with Mylan, "generics," and antitrust. What Plaintiffs were required to do, but did not do, was to draw inferences and adduce evidence tying the actually alleged generic drug conspiracies – either the six drugs attacked as subject to market allocation or the six attacked as having fixed prices – to a loss suffered. Plaintiffs have not done so, and their claims therefore must be dismissed. *See Moody's*, 2013 WL 4516788 at *10. Plaintiffs' failure to "isolate the effect" of the alleged corrective disclosures dooms their claims, particularly given the highly complex and overlapping facts of this case. *Omnicom* I at 554. This is especially pertinent here because "negative characterizations" of already public information – as commonly occurs in filed legal complaints as well as press coverage of controversial industries – are, as a matter of law, insufficient as a basis to find loss causation.

Plaintiffs isolate four triggers purportedly showing loss causation for the generic drugs statements: (1) Trump's January 2017 statement; (2) a November 2016 Bloomberg article; (3) the second amended complaint in a lawsuit filed by a group of state attorneys general (AGs) relating to the generic drug market; and (4) a second lawsuit filed by the same group of AGs in which Mylan was a defendant in May 2019. Each of these fails for reasons irrespective of disaggregation as well.

a. Trump Statement

Nothing in the Trump statement is specific to the generic drug market, let alone Mylan, let alone any of the generic drugs that Plaintiffs have identified on a drug-by-drug basis. Moreover, this statement contains no new information regarding regulatory action. These statements are parallel to similar posturing by politicians that has been rejected in this district as

a sufficient means by which to survive summary judgment in an antitrust action. *See Moody's*, 2013 WL 4516788, at *19 (holding that a senator's statements evincing the mere "potential for bipartisan support of greater regulation" of an industry was insufficient to "reveal[] any new information that effectively materialized the risk of increased regulatory scrutiny" and, therefore, such statements "cannot serve as a proper loss causation event for the purposes of a Section 10(b) claim").

b. Bloomberg Article

Bloomberg published a news article on November 3, 2016. That article reported on an ongoing state attorney general investigation into the generic drug market. Plaintiffs may satisfy the second element necessary to show loss causation (effect on stock price), but they fail to show that this article disclosed anything "new." That Mylan was a target of the investigation was far from new information; it was disclosed, at least, on December 4, 2014, February 16, 2016, May 3, 2016, and August 9, 2016, all well before the Bloomberg article was published.

The Bloomberg article repackaged existing information and so is insufficient to sustain loss causation for securities fraud purposes. "The securities laws require disclosure that is adequate to allow investors to make judgments about a company's intrinsic value. Firms are not required . . . to speculate about distant, ambiguous, and perhaps idiosyncratic reactions by the press" to escape 10b-5 liability. *Omnicom II* at 514. Here, as in *Omnicom II*, a "generalized investor reaction causing a temporary share price decline . . . is *far too tenuously connected* . . . to the [challenged] transaction[s] to support liability." *Omnicom* II at 512, 514. Also as in *Omnicom II*, a holding "otherwise would expose companies . . . to expansive liabilities for events *later alleged to be frauds*, the facts of which were known to the investing public at the time but did not affect share price, and thus did no damage to investors." *Id*. That the article was mere

recharacterization by the press rather than novel revelation is further confirmed by Plaintiffs' own evidence. Plaintiffs rely on commentary on the Bloomberg article by investors that can only be read to suggest an inference that it was a recharacterization, and perhaps more prominent publicization, of information known ahead of time. (*See* P. SOF ¶ 2303 ("Citi . . . . analyst[s] commented that requests for information from 'DOJ pertaining to the marketing and pricing of certain generic products, as well as communications with competitors' had been disclosed by several companies, including Mylan, but it had 'not received much attention until referenced by Bloomberg earlier today.") Plaintiffs' expert even agreed, admitting that "it was already known that there was a large DOJ investigation of the generic pharmaceutical industry and that it included Mylan."[23] (P. SOF ¶ 2306 (quoting Nye Report).)

Plaintiffs argue that another court sustained a loss causation argument against one of Mylan's co-conspirators, Endo, based on the Bloomberg piece. *See Pelletier v. Endo International PLC,* 338 FRD 446, 460 (E.D.N.Y. 2021). But that case is distinguishable. First, in *Pelletier*, the challenged statements were different. Endo's statements suggested that a competitor, not Endo, may have received a subpoena, but the Bloomberg article revealed that to be Endo. *Id.* Second, the *Pelletier* court only held the Bloomberg article contained new information that was material regarding Endo, not Mylan — or even related to any generic drug that Plaintiffs have pleaded sufficiently in this lawsuit. *Id.* at 485 ("The article therefore included new information — the government was scrutinizing generic manufacturers' pricing

[23] The Court assumes without deciding that the Nye Report is admissible and, as such, Defendant's motion *in limine* to exclude it is denied as moot. (ECF No. 381.) Because Defendant's expert S.P. Kothari's proposed testimony exclusively pertained to rebutting Nye and the Court did not rely on Kothari to exclude Nye, Plaintiff's motion to exclude Kothari's testimony is similarly denied as moot. (ECF No. 361.) Likewise, because the Court does not find it necessary to consider it in disposing of Plaintiffs' claims, Plaintiff's motion to exclude the testimony of Daniel Fischel is also denied as moot. (ECF No. 365.)

practices — that was possibly related to Endo's alleged misrepresentations regarding pricing and competition.")

c. AG's Amended Complaint

The AG's amended complaint similarly fails to adduce new information showing a connection between anything Mylan said and new facts. As noted previously, the fact of an investigation into Mylan was public information before the class period. To meet their burden, Plaintiffs must show that new information about Mylan moved the market in excess of previously known information.

Plaintiffs fail to make that showing. Loss causation does not refer to "anything that goes wrong" with a stock. Rather, it is essential that a plaintiff "disaggregate" loss causation arguments in order for courts to credit them, lest all connection with causality fly out the window in a controversial industry. Plaintiffs do not attempt to disaggregate the losses caused by the AGs' complaint's specific allegations about Mylan. Though it would be within the class period, Plaintiffs do not rely in their briefing on the AG's first complaint, filed on December 15, 2016. That first complaint stated that a top executive and director at Mylan was involved with Glazer of Heritage in fixing the prices for Doxy DR. (D. SOF ¶¶ 1115 – 17.)

When the first complaint was filed, Connecticut AG Jepsen, who was leading the investigation, gave a public press conference in which he emphasized that this complaint was "just the tip of the iceberg," and that further allegations of wrongdoing against the defendants and their specific executives were likely forthcoming. (*Id.*) The only new information in the second complaint, then, could be that Malek, then-CEO of Mylan, was this individual. Plaintiffs do not have an expert opinion or other evidence that this minor revelation is what moved the market. And their evidence defeats any remaining possible inference in their favor: The

November 2016 Bloomberg article mentioned that someone like Malik might be charged. It also mentioned the existence of new, parallel AG investigations, likely to be run out of Connecticut. *Id.* ("Jepsen is seeking to lead a group of states to probe the industry, which could result in cases seeking damages.") This article also cites pre-class period statements by Mylan disclosing that they might be "in trouble" regarding Doxy DR. To the extent that the AG complaint expanded the scope of the investigation, it did so with respect to drugs that Mylan did not market, or Mylan did market but Plaintiffs never raised, or which this Court previously dismissed. (MTD Op. II at 14 – 15.) Instead, while the complaint may have expanded the "scope" of the investigation as Plaintiffs claim, it did so only with respect to other firms and other drugs, not any of the drugs that Plaintiffs have pleaded here.

Finally, to the extent that the amended AG complaint disclosed new information, it was new information that this Court has already dismissed in this case. (D. SOF ¶¶ 1123 – 24.) The Court is mindful that "public lawsuits brought by public filings in public courts" are generally said to support a finding of "truth on the market." *White v. H & R Block, Inc.*, 2004 WL 1698628, at *12 (S.D.N.Y. July 28, 2004) (citing *Ganino c. Citizens Utilities Co.*, 228 F.3d 154, 167 (2d Cir. 2000)). Because some significant quantum of this information was disclosed prior to any corrective disclosure or materialization that Plaintiffs identify, it was essential for Plaintiffs to disaggregate new effects and the effects of a new characterization of already filed documents.

d. AG's Second Lawsuit

The second AG lawsuit exclusively concerned drugs that this Court has already rejected in the context of this litigation, so it cannot be a basis to show loss causation as a matter of law. No challenged conduct could have been rendered materially misleading by anything related to

drugs that this Court has dismissed from the litigation; and there has been no proof adduced that the risk materialized and that Defendants knew or should have known what that risk was (here, uncharged antitrust allegations). *See Moody's*, 2013 WL 4516788 at *10 ("To withstand summary judgment," a plaintiff needs some evidence that the defendant's "specified alleged misrepresentations caused the materialization" of the risk that defendants knew or should have known about when they made their misleading statement).

Additionally, AG's second lawsuit concerned 18 drugs, all of which this Court previously dismissed. *See* MTD Op. II at 14. No part of this second lawsuit, then, could establish loss causation with regard to any surviving claims.

V. Conclusion

For the foregoing reasons, Defendants' motion for summary judgment is GRANTED. Plaintiffs' motion for partial summary judgment is DENIED. The outstanding evidentiary motions are DENIED.

The Clerk of Court is directed to enter judgment for Defendants and to close this case.

The Clerk of Court is directed to close the motion at ECF Numbers 292, 325, 360, 361, 365, 367, 371, 372, 376, 378, and 381.

SO ORDERED.

Dated: March 30, 2023
New York, New York

J. PAUL OETKEN
United States District Judge